Surgical Instrument Reprocessing in a Hospital Setting Analyzed with Statistical Process Control and Data Mining Techniques

by

Gail Weart

A Thesis Presented in Partial Fulfillment
of the Requirements for the Degree
Master of Science

Approved April 2014 by the
Graduate Supervisory Committee:

George Runger, Chair
Jing Li
Dan Shunk

ARIZONA STATE UNIVERSITY

May 2014

ABSTRACT

In a healthcare setting, the Sterile Processing Department (SPD) provides ancillary services to the Operating Room (OR), Emergency Room, Labor & Delivery, and off-site clinics. SPD's function is to reprocess reusable surgical instruments and return them to their home departments. The management of surgical instruments and medical devices can impact patient safety and hospital revenue. Any time instrumentation or devices are not available or are not fit for use, patient safety and revenue can be negatively impacted. One step of the instrument reprocessing cycle is sterilization. Steam sterilization is the sterilization method used for the majority of surgical instruments and is preferred to immediate use steam sterilization (IUSS) because terminally sterilized items can be stored until needed. IUSS Items must be used promptly and cannot be stored for later use. IUSS is intended for emergency situations and not as regular course of action. Unfortunately, IUSS is used to compensate for inadequate inventory levels, scheduling conflicts, and miscommunications. If IUSS is viewed as an adverse event, then monitoring IUSS incidences can help healthcare organizations meet patient safety goals and financial goals along with aiding in process improvement efforts. This work recommends statistical process control methods to IUSS incidents and illustrates the use of control charts for IUSS occurrences through a case study and analysis of the control charts for data from a health care provider. Furthermore, this work considers the application of data mining methods to IUSS occurrences and presents a representative example of data mining to the IUSS occurrences. This extends the application of statistical process control and data mining in healthcare applications.

DEDICATION

This work is dedicated to two men whom I love and admire. To Todd, whose unwavering and perpetual support and encouragement made this possible. To my father, who remains a constant source of inspiration and wise counsel.

ACKNOWLEDGMENTS

I would like to thank Dr. Runger for his patience, support, and guidance as I developed and completed a project focused on instrument reprocessing.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

INTRODUCTION

1.0 Introduction

1.1 Pressures on Modern Healthcare Organizations

Healthcare organizations are under pressure to deliver affordable quality services. Financial incentives, voluntary accreditation, regulatory oversight, transparency, and community reputation are motivating factors. One source of financial incentives is the Center for Medicare and Medicate Services (CMS). In 2008 the Center for Medicare and Medicaid Services added surgical site infections to the list of preventable conditions that will not be reimbursed by Medicare. In 2011 CMS announced that Medicaid would not reimburse healthcare organizations for hospital conditions that are considered reasonably preventable. Voluntary accreditations by organizations such as the Joint Commission, Healthcare Facilities Accreditation Program (HFAP), and Det Norske Veritas Healthcare, Inc. (DNV) contain a continuous improvement component. Additionally, accrediting bodies are focusing on instrument reprocessing. Healthcare organizations are also subject to state quality regulations in each state where they conduct business. Finally, with increasing levels of transparency evidenced by the required reporting of hospital acquired infections by thirty states and the District of Columbia (CDC 2013) and the posting of accreditation status by accrediting bodies, hospitals are or should be motivated to improve quality.

1.2 Objective

The goal of this work is to apply statistical process control (SPC), specifically control charts to Sterile Processing Department (SPD) data in an effort to better understand the process with the hope of identifying opportunities for improvement. This work looked at the occurrence of immediate use steam sterilization (IUSS) in a suburban hospital. Specifically, a calendar year of retrospective data was evaluated with statistical tools to understand the current state of the process. Monitoring tools were applied to the data, an evaluation of the process was completed, and opportunities for improvement were presented. Data mining techniques were presented as a tool to understand which factors influence IUSS.

CHAPTER 2

BACKGROUND

2.1 Operating Room Contribution

Within a healthcare organization, the Operating Room (OR) is an important department because of the enormous contribution to revenue, but also for sizable overhead cost and the potential impact on hospital acquired infections (HAI). While surgery is estimated to generate about two thirds of a hospital's revenue (Jackson 2002), it is also estimated to account for about one third of hospital resource costs (Macario et al. 1995). Hospitals make substantial investments in their surgical instrument inventories, along with their OR equipment and SPD equipment. For example, a typical 350-bed hospital that performs about 11,000 surgeries per year can have an instrument inventory that exceeds five million dollars. The mobile electrical medical devices along with their requisite cables, cords, and operating interfaces can be an additional one million dollars (Brooks 2010). Healthcare organizations also make substantial capital investment for the equipment required to reprocess instruments (cart washers, instrument washer/disinfectors, ultrasonic cleaners, automatic endoscope reprocessors, steam sterilizers, low temperature sterilizers). Hospitals are also investing in Hospital Information Management Systems (HIMS) for instrument tracking, which can cost several hundred thousand dollars (Frost and Sullivan n.d.). When fully integrated, instrument tracking systems interface with other HIMS including surgery scheduling software and can flag issues regarding insufficient instrumentation (Williamson 2011).

2.2 Sterile Processing Department Contribution

In a healthcare setting, SPD provides ancillary services to the OR, Emergency Room, Labor & Delivery, and off-site clinics, with the OR being the largest customer. This support function has been getting more attention in recent years as healthcare organizations seek to improve operating room efficiencies, reduce hospital acquired infections, maintain accreditations, and use more complex and costly surgical instruments.

While this department can be called several names, including the Sterile Processing Department (SPD), Central Services (CS), Central Sterile Processing Department (CSPD), and

Central Sterile (CS), its function remains the same – to reprocess reusable medical instruments and equipment then return them to their home departments. In this document the initials SPD will be the used to refer to the reprocessing department.

The general reprocessing cycle consists of six steps. They are receiving, decontaminating/cleaning, packaging, sterilizing, storing, and issuing. While there are several methods for sterilization, this work is limited to instruments and devices that are sterilized with steam.

2.3 OR / SPD Relationship and the Reprocessing Cycle

SPD and the OR must work closely because each is a customer and a supplier in the reprocessing cycle. The OR supplies SPD with its raw materials in the form of soiled surgical instruments. Therefore, the OR is the supplier and SPD is the customer at the beginning of the cycle. SPD returns sterile instruments to the OR, therefore in turn, SPD becomes the supplier and the OR is the customer at the end of the cycle. The success of the instrument reprocessing cycle is dependent upon this cooperation and is imperative for an organization to meet and hopefully exceed its financial, efficiency, and patient safety goals.

Multiple factors influence the success of the instrument reprocessing cycle including the relationship between the OR and SPD, the relationship of the hospital and its medical device vendors, the availability and the sharing of information, the instrument inventory levels in various departments, competency of the OR staff, competency of the SPD staff, and staffing levels.

The relationship between the OR and SPD is often strained. The pressure to turn over rooms for surgery, lack of communication regarding instrumentation needs, inadequate time to process vendor trays, lack of understanding regarding the time needed to properly process trays, along with the lack of linkage between surgery needs and actual instrument inventories contributes to this strained relationship. Both the OR and SPD are victims of inadequate resources (e.g. instrumentation) due to surgery scheduling demands.

Medical device vendors that provide loaner instrumentation to hospitals contribute to the strained relationship between the OR and SPD. When loaner trays arrive with inadequate reprocessing information and/or the time to properly process trays, they become a source of

stress. In general, the rule of thumb is three hours to process and terminally sterilize instruments (Brooks 2011; Smart, Belkoff, and Mears 2012). Manufacturer's Instructions for Use (IFU) provide information on reprocessing including cleaning and sterilization requirements. New emphasis on the availability of and adherence to IFUs by regulatory and accreditation bodies has increased awareness and compliance.

Information and communication are crucial to the success of device reprocessing. HIMS for instrument tracking that are fully integrated with surgery scheduling HIMS greatly improve the device reprocessing cycle. Integrated systems can automatically flag resource issues before they have a chance to negatively impact the surgery schedule by causing costly delays and cancellations (Williamson 2011).

The surgeon and the OR staff are experts at executing surgeries which includes the use of instrumentation. While an OR nurse may be an expert in one type of surgery and its instrumentation, SPD must have a broader knowledge because the SPD staff reprocess the instruments for all of the surgery specialties. Thus, SPD is the expert regarding the care and sterilization of surgical instrumentation and equipment. Appreciating, respecting, and drawing on the synergy of their respective core competencies can strengthen the relationship between the OR and SPD.

While nursing requires a college degree, sterile processing is considered an entry level healthcare position. SPD technicians can enter the field with a high school diploma or GED and receive on the job training. A survey posted on the International Association of Healthcare Central Service Materials Management (IAHCSMM) website (n= 531) states that only about one third of responding hospitals require certification, however approximately forty percent plan to require certification in the future (IAHCSMM 2011). "Certification is a recognized method of initially determining competency" (AAMI 2010). The two major organizations that offer certification are IAHCSMM and CBSPD (Certification Board of Sterile Processing Professionals). The sterile processing profession is actively working to meet the increasing requirements and expectations placed upon them. In an effort to raise the bar for sterile processing professionals, IAHCSMM is working with states to pass legislation that would require sterile processing

professionals to become certified. To date, New Jersey and New York are the only states that require sterile processing certification. Medical professionals working with certified SPD professionals can foster a healthy peer respect and promote improved relations and communication to alleviate interdepartmental stress.

A final contributing factor to the success of the reprocessing cycle is the staffing levels of both the OR and SPD. Inadequate staffing can cause personnel to rush, make errors, and possibly curtail established hospital procedures. Thus, what seems like a minor staffing problem can lead to a patient safety issue and the costs that accompany such issues.

A logical conclusion would be that the effective management of the medical device reprocessing cycle can positively impact the OR's ability to generate revenue and contribute to patient safety. It follows that reducing the number and frequency of events that impede the OR's ability to function efficiently would also positively impact the OR's ability to generate revenue and contribute to patient safety.

When instrumentation or devices are not available or are not fit for use, the OR's ability to operate efficiently is impeded. Time taken by personnel to search for missing instruments or retrieve replacements for malfunctioning, improperly processed, or soiled instruments can delay surgery starts, cause surgery cancellations, increase the time that a patient is under anesthesia, or cause a surgeon to use an alternate instrument. Inadequate time to process and terminally sterilize instruments can increase the incidents of IUSS. If IUSS is viewed as an adverse event or defect, then monitoring these events/defects can aid organizations in process improvement efforts. As the process improves the incidence of adverse events and rate of defects should decrease.

2.4 Immediate Use Steam Sterilization

The general instrument reprocessing cycle consists receiving, decontaminating/cleaning, packaging, sterilizing, storing, and issuing. The IUSS process abbreviates the instrument reprocessing cycle by, at minimum, replacing the terminal sterilization cycle with an IUSS cycle. The decontamination step may be abbreviated to expedite an instrument through the reprocessing cycle for IUSS. In addition, the packaging step can be modified and the storage

step is eliminated for IUSS. The sterilization step is also abbreviated by reducing or eliminating the dry time at the end of the sterilization cycle. The unwrapped item categories in Table 1 and Table 2 are the IUSS cycles. Note that the drying time for the Dynamic-Air Removal (DAR) IUSS steam sterilization cycles in Table 1 has been eliminated and the drying time for the IUSS Gravity steam sterilization cycles in Table 2 has been reduced.

Table 1 Minimum Cycle Times for Dynamic-Air Removal Steam Sterilization Cycles

Item	Exposure time at 132°C (270°F)	Exposure time at 135°C (275°F)	Drying times
Wrapped instruments	4 minutes		20 to 30 minutes
		3 minutes	16 minutes
Textile packs	4 minutes		5 to 20 minutes
		3 minutes	3 minutes
Wrapped utensils	4 minutes		20 minutes
		3 minutes	16 minutes
Unwrapped nonporous items (e.g., instruments)	3 minutes	3 minutes	NA
Unwrapped nonporous and porous items in mixed load	4 minutes	3 minutes	NA

NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

Source: Data from (AAMI 2010).

Table 2 Minimum Cycle Times for Gravity-displacement Steam Sterilization Cycles

Item	Exposure time at 121°C (250°F)	Exposure time at 132°C (270°F)	Exposure time at 135°C (275°F)	Drying times
Wrapped instruments	30 minutes	15 minutes		15–30 minutes
			10 minutes	30 minutes
Textile packs	30 minutes	25 minutes		15 minutes
			10 minutes	30 minutes
Wrapped utensils	30 minutes	15 minutes		15–30 minutes
			10 minutes	30 minutes
Unwrapped nonporous items (e.g., instruments)		3 minutes	3 minutes	0–1 minute
Unwrapped nonporous and porous items in mixed load		10 minutes	10 minutes	0–1 minute

NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

Source: Data from (AAMI 2010).

Immediate use steam sterilization, formally called flashing or flash sterilization, refers to the process used for patient care items not intended to be stored for future use. In contrast, items undergoing terminal sterilization can be stored and are considered sterile until an event renders them unsterile. Steam sterilization is the sterilization method used for IUSS (AAMI 2010). Therefore, this work only considered items sterilized by steam. The Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN), International Association of Healthcare Central Service Material Management (IAHCSMM), the Centers for Disease Control (CDC), and Food and Drug Administration (FDA) all discourage IUSS to compensate for inadequate instrument inventories or convenience.

While the sterilization parameters used for IUSS cycles are valid and provide sterile instruments, the concern comes from the potential for staff to skip a step or rush through the cleaning and preparation steps that are critical and must occur prior to sterilization. Additional concerns result from the potential for contamination during transport of the instruments from the sterilizer to the sterile field.

One reason to minimize IUSS is the potential correlation of IUSS to surgical site infections (SSI). Although it is difficult to determine the exact cause of a SSI, potential correlations have been made between IUSS and SSI (Leonard et al. 2006; Smart, Belkoff, and Mears 2012; Zuckerman et al. 2012). Gruskay et al. (2012) stated that IUSS sterilization is a factor that must be considered in evaluating risk of infection. Richmond et al. (2009) reported that spinal surgeries were 5.3 times more likely to have had an item that underwent IUSS than a control group that did not have items that underwent IUSS. As a result of the concerns regarding IUSS, healthcare organizations actively try to reduce the rate of IUSS (Leonard et al. 2006; Martin and Beck 2004; Richmond et al. 2009; Smart, Belkoff, and Mears 2012). Smart, Belkoff, and Mears (2012) documented efforts to reduce the IUSS rate for total hip and knee arthroplasties at an academic medical center. After an eleven month effort, the IUSS rate for total hip and knee arthroplasties reached zero percent, which was maintained for the last three months of the reported data. Smart, Belkoff, and Mears (2012) calculated the IUSS rate as a percent of total surgeries that used items that were sterilized for immediate use. At the end of the yearlong study

the committee had achieved a statistically significant reduction in the IUSS rate ($P<0.05$), reducing IUSS from 6 out of 34 surgeries to 0 out of 41 surgeries. While the authors state that they continue to monitor the IUSS rate and facilitate communication they do not mention any tools that will allow them to determine if the process remains in control. Control charts can assist in these efforts and help use resources efficiently by having staff react only when the rate has actually changed.

The costs associated with SSIs are significant. Stone (2009) reported that there are 290,485 surgical site infections annually with a mean death rate of 13,088 per year for these SSI. Scott (2009) reviewed the literature and reported that the cost of SSI range from $11,874 to $34,670. These costs were calculated using the Consumer Price Index (CPI) for urban consumers (CPI-U) and the CPI for inpatient services and reported in 2007 dollars.

Given the cost of SSI and its potential correlation with IUSS, minimizing IUSS for non-emergent situations is in the best interest of the healthcare organization and the patient. While there is no established industry standard, the American Academy of Orthopedic Surgeons Research Committee recommended a standard benchmark rate of 1% for immediate use steam sterilization (Leonard et al. 2006). In an article sharing an SPD scorecard that used the rate of IUSS as a metric, Narance (2008) stated 5% as an industry average and 3% as an industry best for the rate of IUSS. No sources for the IUSS rates were cited by Narance (2008). For the scorecard Narance (2008) calculated the IUSS rate as the percent of instrument trays undergoing IUSS as compared to the total trays processed.

2.5 Healthcare and Statistical Process Control

Healthcare and epidemiology monitor the occurrence of adverse events. Extending adverse event monitoring into the hospital device reprocessing cycle can provide healthcare organizations a means to understand, monitor, and reduce the occurrence of IUSS. Examining the reasons and items of IUSS may provide a deeper understanding and additional opportunities to reduce IUSS for non-emergent situations.

The application of statistical process control in healthcare continues to be a dynamic topic. A review by Thor et al. (2007) of SPC applications in healthcare concluded that SPC is a

versatile quality improvement tool that has been broadly applied in healthcare. A database search provided 311 references, of which 57 were included in the review. These 57 articles showed application in a variety of healthcare settings across 20 healthcare specialties, monitoring 97 variables. The healthcare settings included hospitals, outpatient clinics, laboratories, nursing homes, and mental health residential facilities with specialties including surgery, nursing, cardiology, orthopedics, oncology, radiology, and pediatrics. Thor et al. (2007) classified the variables as biomedical, biomedical measurement variables, other variables related to patient health, and clinical management variables. Variables were monitored in a variety of ways, including the time between events, rate of events, and the number of events. Specific examples include HbA_{1c} level in groups of diabetic patients, blood pressure measurement error (mm Hg), days between asthma attacks, and the proportion of low birth weight infants.

Statistical process control employs control charts which are tools to help mangers make decisions and develop protocols. The proper use of control charts starts with understanding the underlying distribution in order to choose the appropriate control chart, constructing a trial chart to determine if the process is in control, and removing the special cause variation. Failure to complete these preliminary steps can lead to incorrect conclusions regarding the state of statistical control of a process. Aggregating data on control charts can also lead to incorrect conclusions and missed opportunities for improvement (Benneyan and Kaminsky 1994; Kaminsky et al. 1992).

Benneyan (1998a; 1998b) published a two part article titled “Statistical Quality Control Methods in Infection Control and Hospital Epidemiology” in which he draws parallels between SPC and Epidemiology, covers the basic principles of SPC, and shares several applications from Epidemiology. A p chart for the rate of catheter-associated infections per month based on unequal subgroup size was included as an example application. The monthly subgroup size is unequal because the number of catheterizations varied from month to month (Benneyan 1998a). The number of open heart surgeries between postoperative sternal-wound infections was presented as an example application of a g chart (Benneyan 1998b).

2.6 Attribute Control Charts

Attribute control charts are used to monitor count data. The fraction or rate of nonconformance can be monitored or the number of nonconformities can be monitored. The p and np control charts are used to monitor the fraction nonconforming. The c and u control charts are used to measure nonconformities. The cumulative sum (CUSUM), exponentially weighted moving average (EWMA), and time between charts can be used to measure small shifts (Montgomery 2009). The binomial distribution is the distribution on which the p and np control charts are based. The Poisson distribution is the distribution on which the c and u control charts are based. The geometric distribution is the distribution on which the g and h time between control charts are based (Montgomery 2009). This work considered the p and g control charts for IUSS monitoring.

The p chart, or fraction nonconforming control chart, monitors the ratio of the nonconforming items to the total number of items. When p for the process in not known, it must be estimated from the observed data. The fraction nonconforming control limits for a variable sample size are given by (Montgomery 2009):

$$UCL = \acute{p} + 3\sqrt{\frac{\acute{p}(1-\acute{p})}{n_i}}$$

$$Center\ Line = \acute{p}$$

$$LCL = \acute{p} - 3\sqrt{\frac{\acute{p}(1-\acute{p})}{n_i}}$$

Where n_i = size of the i^{th} subgroup
$\acute{p}$ = estimate of the fraction nonconforming

The g chart, also known as the time between control chart, monitors the time between events of interest. Benneyan (2001) advocates the use of geometric control charts for monitoring adverse events in healthcare because they "can exhibit improved shift-detection sensitivity over conventional approaches, particularly when dealing with infrequent events or low "defect" rates." He does note that g charts are "not very helpful in detecting increased rates of" adverse events.

The control limits for the geometric control chart are given by (Montgomery 2009):

$$UCL = n\left(\frac{1-\acute{p}}{\acute{p}} + a\right) + L\sqrt{\frac{n(1-\acute{p})}{\acute{p}^2}}$$

$$Center\ Line = n\left(\frac{1-\acute{p}}{\acute{p}} + a\right)$$

$$LCL = n\left(\frac{1-\acute{p}}{\acute{p}} + a\right) - L\sqrt{\frac{n(1-\acute{p})}{\acute{p}^2}}$$

Where

a = known minimum possible number of events
n = subgroup size
$\acute{p}$ = estimate of p
L = number of standard deviations used in the control limits

The parameter a is minimum number of events and is related to the Bernoulli process. When a = 1, the control chart will display the number of days/items (Bernoulli trials) until the next adverse event. When a = 0, the control chart will display the number of days/items (Bernoulli trials) before the next adverse event (Benneyan 2001).

CHAPTER 3

THE IMMEDIATE USE STEAM STERILIZATION PROCESS AND CONTROL CHARTS

If an IUSS event is viewed as a defect in the instrument reprocessing cycle, then attribute control charts are appropriate to monitor the process. Specifically, a fraction nonconforming control chart will monitor the ratio of items undergoing IUSS to all steam sterilized items. The geometric control chart will monitor the time between the IUSS events.

The reasons for IUSS can be broken down into three categories. Refer to Figure 1. These categories are 1) the Return of either patient explants or the return of loaner/consignment items, 2) Processing/Technique errors, and 3) Scheduling/Communication errors.

The Return category includes the return of hardware (plates, screws, rods) removed from a patient then given back to that patient. The Return category also includes the return of instruments loaned to the hospital, or other consignment items.

The Processing/Technique category has three subcategories. The first subcategory is Package Integrity. When the packaging integrity is compromised by a hole, tear, or poor seal, then the instruments are considered unsterile. If a terminally sterilized replacement is not available, then the item must undergo IUSS. The second subcategory is Contaminated. When an instrument is dropped or otherwise leaves the sterile field, it is considered contaminated during surgery. If a terminally sterilized replacement is not available, then the item must undergo IUSS. Third subcategory is Other. Other reasons that instruments are considered unsterile include rigid containers that are missing filters, missing locks, or have broken locks. Instruments are also considered unsterile if the indicator is missing, an indicator has not changed color, or a sterilization cycle was run using the incorrect parameters. If terminally sterilized replacements are not available, then the items must undergo IUSS.

The Scheduling/Communication category has two subcategories. The first subcategory is Late. Loaner instrumentation that arrives with insufficient time to go through the complete, unabbreviated device reprocessing cycle through SPD, which includes terminal sterilization, must undergo IUSS. Instrumentation may be loaned to a hospital from a vendor, another hospital, or other organization. The second subcategory is Turnover. Inadequate instrumentation inventory

and the related topic of surgery scheduling result in insufficient time for instruments to go through the complete, unabbreviated device reprocessing cycle in SPD, which includes terminal sterilization. When this happens, instrumentation must be expedited through the reprocessing cycle. This expedited and often abbreviated reprocessing cycle does not allow for terminal sterilization in SPD, but rather IUSS in the OR. The need to turnover instruments quickly occurs when instrumentation is needed for another case later in the day, but there is insufficient time (less than three hours) for the instrumentation to go through the complete, unabbreviated device reprocessing cycle in SPD, which includes terminal sterilization. This happens when there is inadequate instrument inventory to accommodate the number of surgeries and those surgeries were scheduled with insufficient time for the instrumentation to go through the complete, unabbreviated device reprocessing cycle through SPD, which includes terminal sterilization. When the complete reprocessing cycle is conducted in the sterile processing department it consists of receiving, decontaminating/cleaning, packaging, sterilizing, storing, and issuing. Given that IUSS should only be used in emergency situations, IUSS should be an infrequent occurrence. If IUSS is viewed as an adverse event or defect, then IUSS is categorized as discrete data. The IUSS rate and the time between the IUSS occurrences are important measurements because they capture multiple issues relating to the instrument reprocessing cycle. Monitoring IUSS can provide feedback regarding instrument inventories, processing errors, and scheduling conflicts. Monitoring IUSS over time will detect process changes, thus support continuous improvement efforts and help an organization meet its patient safety and financial goals.

Two types of control charts were developed, a p chart for the fraction nonconforming and a g chart for the time between IUSS events. The return events were removed because they do not impact surgeries or patients.

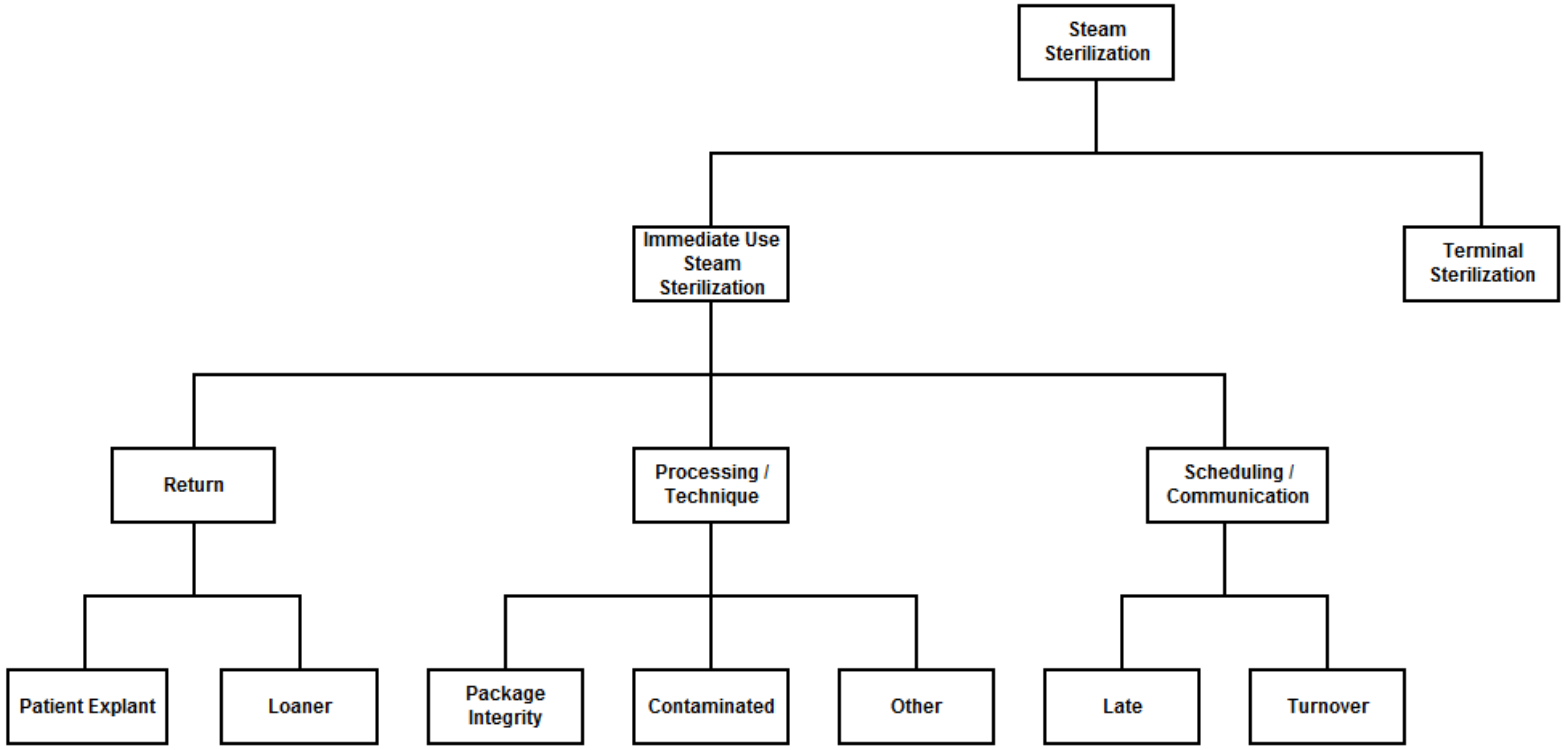

Figure 1 Categories of Steam Sterilization

The fraction nonconforming for the p chart can be calculated several ways. The fraction non-conforming for IUSS can represent the proportion of surgeries that had one or more items that underwent IUSS or it can represent the proportion of items that underwent IUSS. The fraction nonconforming would be expected to larger for the fraction of nonconforming surgeries versus steam sterilized items because there are often multiple items and/or instrument sets that get used on each surgery. In this work, the fraction nonconforming is calculated as the proportion of items that underwent IUSS.

Weekly monitoring of the IUSS rate was chosen for the IUSS fraction nonconforming control chart. Weekly monitoring provides timely feedback while providing a stable sample size. Daily monitoring would not provide a stable sample size because the number of surgeries performed on the weekends is generally less than the number of surgeries performed during the week. While some surgeries are scheduled for weekends, most surgeries performed on weekends are emergent, resulting in lower surgery volumes on Saturdays and Sundays. Since the fraction nonconforming is calculated using the total number of steam sterilized items, and the number of items will vary from week to week based on the volume and types of surgeries performed, a p chart with variable control limits was used to accommodate the variable sample size.

A geometric control chart was developed for the IUSS data. If IUSS occurrences are viewed as adverse events, then as Benneyan (2001) suggests, a g chart is an appropriate choice. IUSS occurrences should be infrequent if appropriate inventory levels are sustained and effective communication is in place between the OR and SPD.

Initial or trial limits were developed and sensitizing rules for Shewhart control charts from Table 3 (Montgomery 2009) were used to evaluate the trial periods.

Table 3 Sensitizing Rules for Shewhart Control Charts

1. One or more points outside the control limits.
2. Two of three consecutive points outside the two-sigma warning limits but still inside the control limits.
3. Four out of five consecutive points beyond the one-sigma limits.
4. A run of eight consecutive points on one side of the center line.
5. Six points in a row steadily increasing or decreasing.
6. Fifteen points in a row in zone C (both above and below the center line).
7. Fourteen points in a row alternating up and down.
8. Eight points in a row on both sides of the center line with none in zone C.
9. An unusual or nonrandom pattern in the data.
10. One or more points near a warning or control limit.

CHAPTER 4

CASE STUDY WITH CONTROL CHARTS

4.1 Data Source

The data for this project came from a suburban hospital with 176 beds and eight operating rooms. There are four sub-sterile rooms shared among the eight operating rooms. Each pair of operating rooms shares one sub-sterile room. The autoclaves used for IUSS are located in the sub-sterile rooms**.** The data for this project came from two sources. The IUSS information was extracted from the sterilizer logs located in the four sub-sterile rooms in the OR. The number of items processed per day came from SPD records. Only steam sterilized items were included. Items that were high level disinfected or hydrogen peroxide gas plasma sterilized were not included. Twelve months of data regarding the volume of items processed by SPD and data from the OR IUSS logs was used.

After a review of the information extracted from the sub-sterile logs, the information was categorized. Although some of the log entries were vague, IUSS events were categorized into one of three IUSS categories. The categories, as discussed previously are: 1) the Return of either patient explants or the return of loaner/consignment items, 2) Processing/Technique errors, and 3) Scheduling/Communication errors. Each log entry was further classified as to the IUSS subcategory and the ownership of the item. Refer to Figure 1 for steam sterilization categories and subcategories.

4.2 Data Summary

The data from the IUSS logs are summarized in the figures below. Figure 2 shows that the vast majority of IUSS cycles fall into the Scheduling/Communication category. If insufficient instrument inventories exist to accommodate the number or order of surgeries scheduled, instruments may need to undergo IUSS to compensate for the insufficient inventories. Figure 3 shows that the turnovers account for the majority of the Scheduling/Communication category. Insufficient inventory necessitates the need to turnover instrument sets for another surgery. Figure 4 shows the breakdown of the Processing/Technique IUSS category. Contaminated

instruments, package integrity, and other miscellaneous reasons are the subcategories for the Processing/Technique IUSS category. Figure 5 shows the ownership of the instruments that underwent IUSS. The majority of the items that underwent IUSS were hospital owned. From these summary graphs, the statement that most IUSS occurrences were the result of scheduling/ communication issues which then necessitated the turnover hospital-owned instruments with expedited reprocessing steps can be made. Tracking the specific items that underwent IUSS will help organizations determine which instruments are in high demand and thus help them make sound financial decisions regarding future instrument purchases. Investigating the package integrity and other subcategories of the Processing/Technique events for special causes would improve the process. The review and investigation of IUSS occurrences and items should be timely to be most effective. Given the volume and nature of the work performed by the OR and SPD waiting too long will make investigations challenging. For example, if IUSS logs are not filled in completely or contain vague information, extended periods between log reviews may limit the amount of information that can be recovered. Frequent log reviews will help OR and SPD staff understand the requirements and develop attention to detail. Weekly versus monthly or quarterly investigations would facilitate data gathering and recovery. In addition, as HIMS become more integrated, the hope is that integrating the scheduling HIMS and the instrument tracking HIMS may help reduce the number of IUSS. If HIMS are integrated, the system could flag potential instrumentation conflicts allowing for resolution and avoid IUSS.

As an interesting coincidence, the reasons and frequency for IUSS from this project aligned with the reasons and frequencies reported by Leonard et al. (2006). Table 4 presents the reasons by percent for IUSS from Leonard et al. (2006) with the reasons by percent from this work. In both works, the need to turnover instrumentation from a previous surgery was by far the largest reason for IUSS. In addition, the contaminating/dropping an instrument ranked higher than package integrity/torn wrappers. The failed integrator/other processing/ technique category had the lowest frequency of occurrence.

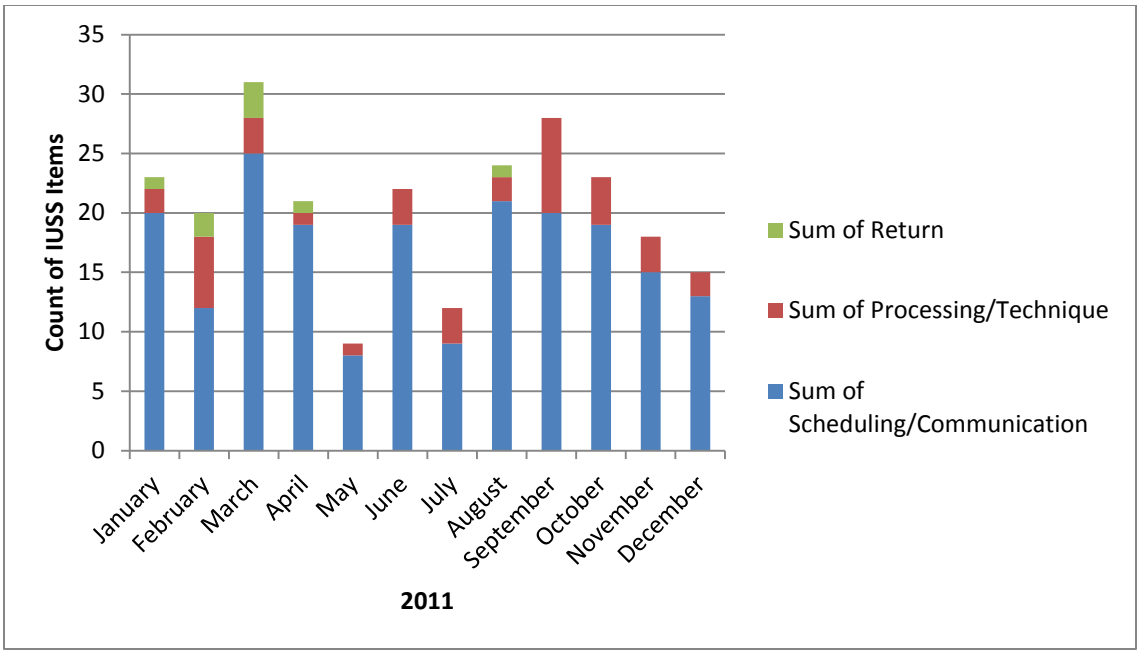

Figure 2 Count of Immediate Use Steam Sterilization Items by Month

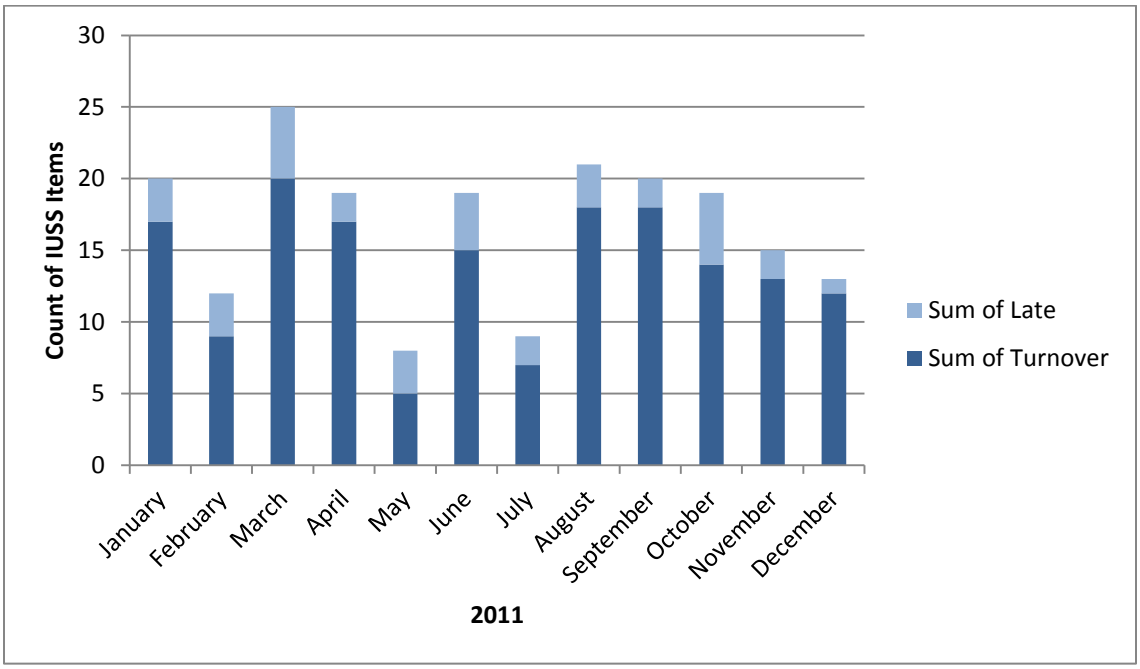

Figure 3 Count of Scheduling/Communication IUSS Items by Month

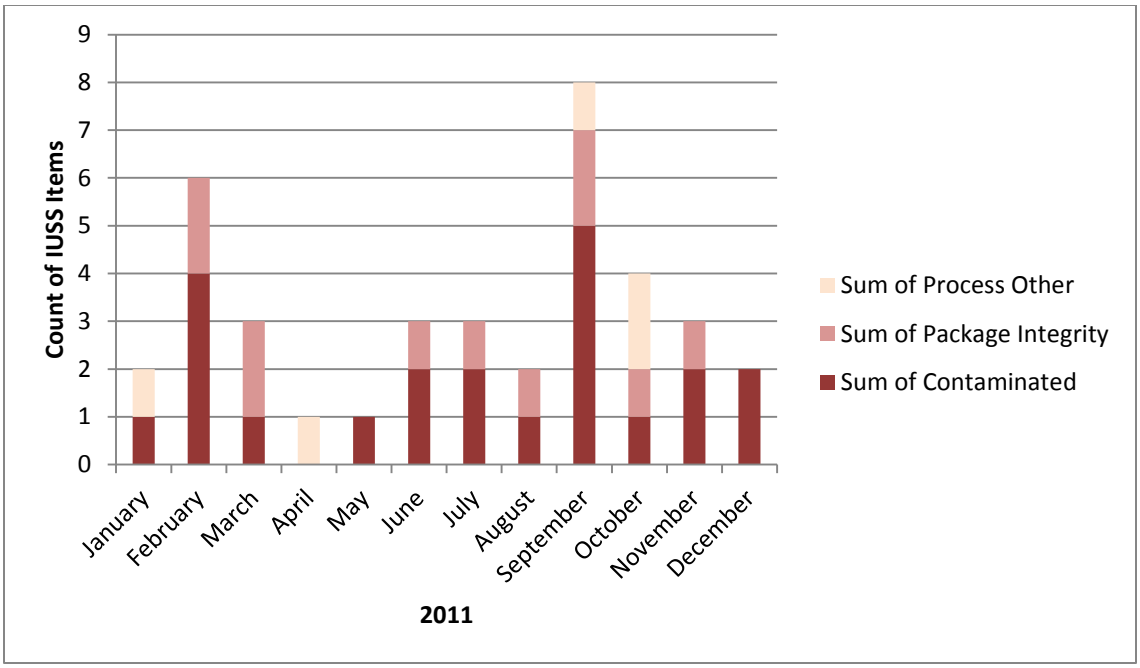

Figure 4 Count of Processing/Technique IUSS Items by Month

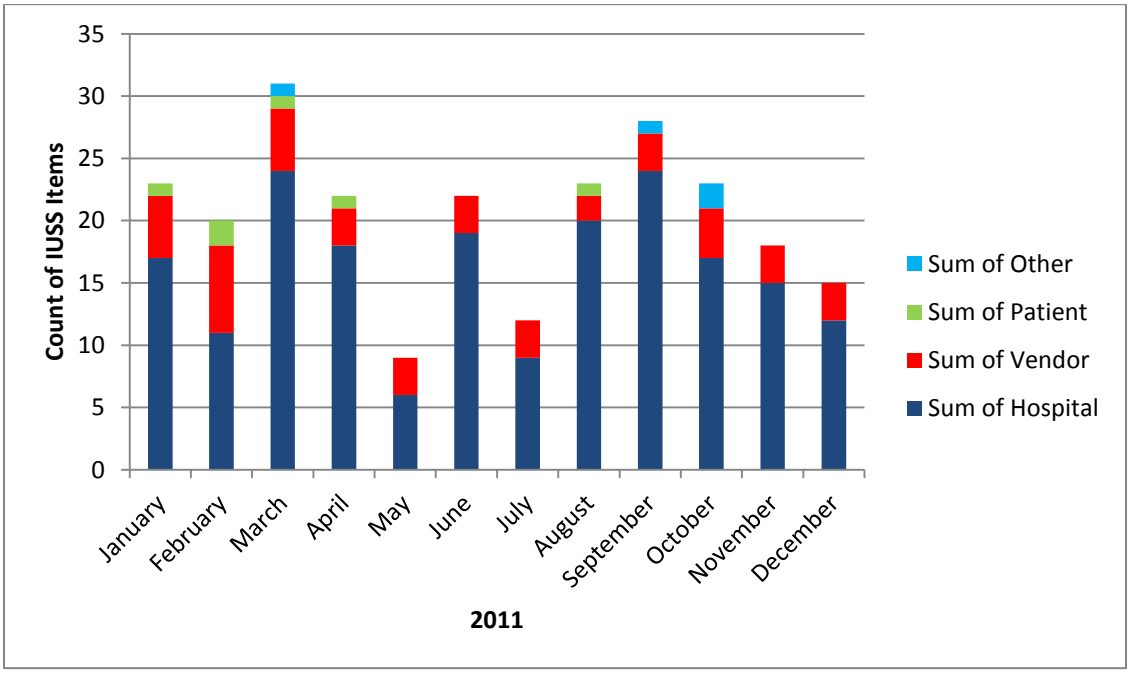

Figure 5 Count of Ownership of IUSS Items by Month

Table 4 Comparison of IUSS Reasons by Percent for Leonard et al. and This Work

IUSS Reason		Percent	
Leonard et. al.	**This work**	**Leonard et. al.**	**This work**
Instrument from previous procedure needed and not available	Scheduling/Communication/ Turnover	77.7	69.3
Other	Scheduling/Communication/ Late	9.9	14.7
Dropped single item	Processing/Technique/ Contaminated	8.3	9.2
Torn Wrapper	Processing/Technique/ Package Integrity	3.3	4.6
Indicator failure as noted by a reject on the chemical indicator strip	Process/Technique/Other	0.8	2.1
	Total	100.00	100.00

Source: Data from (Leonard et al. 2006).

4.3 Fraction Nonconforming Chart for Weekly IUSS Rates

The daily IUSS data was aggregated into weeks for the p chart. Weekly feedback is timely as opposed to monthly or quarterly. Researching events that occurred in the previous month or quarter is more challenging than researching events that occurred in the previous week given the volume and nature of work performed by the OR and SPD.

Figure 6 shows the p chart for the Processing/Technique and the Scheduling/Communication categories of IUSS events. Thirty points were used to develop the trial or initial center line and control limits. The process was in control, with no points outside the control limits and no nonrandom patterns for the trial period. The process went out of control during week 52 given that two of three points are beyond the 2 sigma limits, violating the second sensitizing rule found in Table 3. For this application, monitoring IUSS occurrences, the process going out of control by falling below the lower limits is desirable because the goal is to reduce the IUSS rate. Even though a rate reduction is desirable, the cause must be investigated. Since this is retrospective data, no investigation can be conducted. One possible explanation for the 0 IUSS

rates in weeks 47, 51, and 52 is that major United States holidays fell in those weeks. The Thanksgiving holiday fell in week 47, the Christmas holiday fell in week 51, and the New Year's holiday fell in week 52. Surgical volumes may have been down during those weeks resulting in less need for expedited instruments.

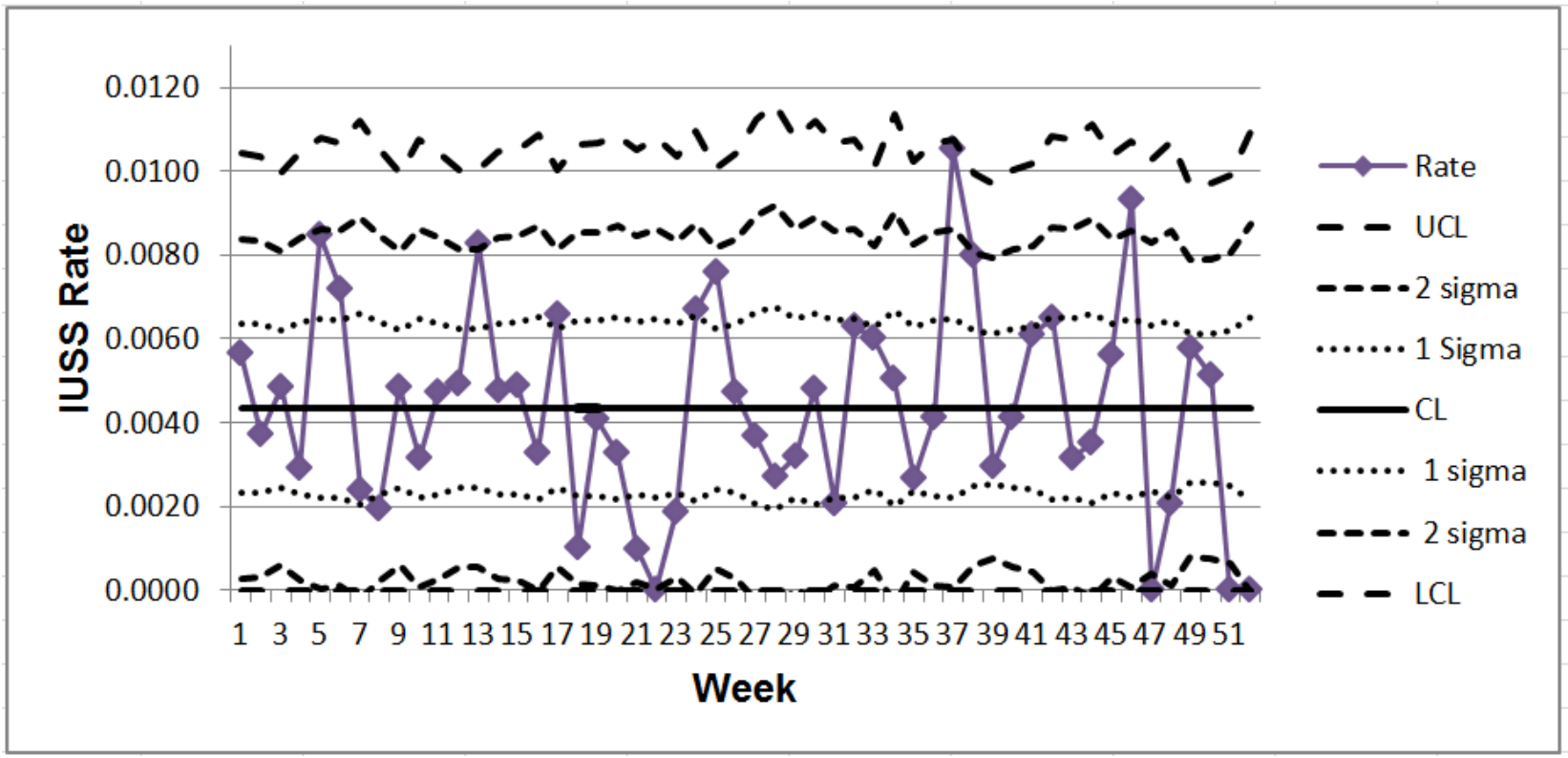

Figure 6 p chart for Weekly IUSS Rates

4.4 Geometric Control Charts for IUSS

A geometric control chart was developed for the overall IUSS process. In addition, the IUSS process was stratified and g charts were developed for the major categories: Processing/Technique and Scheduling/Communication. The IUSS process was further stratified by developing g charts for some of the subcategories. A g chart was developed for the Contamination subcategory of the Processing/Technique category, the Late subcategory of the Scheduling/Communication category, and the Turnover subcategory of the Scheduling/Communication category. Geometric control charts were not developed for the Package Integrity and Other subcategories of the Processing/Technique category because there were too few occurrences to develop control charts. All the g charts were developed using sigma limits versus probability limits because sigma limits are well understood.

Figure 7 shows the g chart for the Processing/Technique and Scheduling/Communication categories combined. Fifty-one points were used to develop the trial or initial center line and control limits. The process was not in control. There were multiple instances that violated rule 2 of the Sensitizing Rules for Shewhart Control Charts listed in Table 3. Rule two states “Two of three consecutive points outside the two-sigma warning limits but still inside the control limits.” Seven sets of points lie on the LCL. Since there is not a one or a two sigma limit on the lower side of the control chart and the LCL is equal to zero, the fact that two of three consecutive points are on the LCL indicates that the process was not in control. When monitoring IUSS occurrences with a g chart, falling out of control on the lower side of the control chart, with more IUSS events occurring closer together, is an indication of process degradation and should be investigated. In contrast, process improvement is indicated by IUSS incidents occurring less frequently. When the IUSS process goes out of control on the top side of the control chart, with IUSS incidents occurring less frequently, the cause(s) should be investigated and continued. Again, because this was retrospective data and no investigation could take place regarding the out of control points, the initial limits were left in place. These initial control limits were extended to the remainder of the data. The process remained out of control.

Figure 8 shows the g chart for Processing/Technique IUSS events. Thirty points were used to develop the trial or initial center line and control limits. The process was not in control. There were three instances that violated rule 2 of the Sensitizing Rules for Shewhart Control Charts listed in Table 3. Rule two states "Two of three consecutive points outside the two-sigma warning limits but still inside the control limits." Two sets of points lie on the LCL and one set of points lies between the upper 2 and 3 sigma limits. Since there is not a one or a two sigma limit on the lower side of the control chart and the LCL is equal to zero, the fact that two of three consecutive points are on the LCL indicates that the process was not in control. As this was retrospective data and no investigation could take place regarding the out of control points, the initial limits were not revised. These initial control limits were extended to the remainder of the data. The next eight points appear to be in control, with no points beyond the control limits and no non-random patterns.

Figure 9 shows the g chart for Contamination subcategory of the Processing/Technique IUSS events. Twenty-two points were used to develop the trial or initial center line and control limits. The process was in control. There were no points beyond the control limits and no non-random patterns. A review of the items that underwent IUSS due to contamination in the OR may indicate opportunities to improve the process. Identifying the items that are routinely contaminated and ensuring that sterile replacements are available may decrease the need to use IUSS. If a review indicates that a specific type of surgery or instrument routinely become contaminated, an opportunity for training the OR staff on the use of the instrumentation may be appropriate.

Figure 10 shows the g chart for Scheduling/Communication IUSS events. Fifty-four points were used to develop the trial or initial center line and control limits. The process was not in control. There were two points of the first fifty-four that fell beyond the upper control limits. In addition there were eight instances when at least two of three consecutive points fell on the lower control limits. As this was retrospective data and no investigation could take place regarding the out of control points, the initial limits were not revised. These initial control limits were extended

to the remainder of the data. The process remained out of control for the remainder of the time it was monitored.

Figure 11 shows the g chart for the Late subcategory of the Scheduling/Communication IUSS events. Thirty points were used to develop the trial or initial center line and control limits. The process was not in control. There was one instance of rule 2 from Table 3 being broken. The process was in control after the trial period with no points beyond the control limits and no non-random patterns. Investigating the reason(s) why there were 0 days between IUSS for Late items and working to prevent such incidents can help improve the process. If the events that led to 0 day periods between IUSS are not due to emergencies, then better coordination with vendors, the OR, and SPD should help improve the process.

Figure 12 shows the g chart for Turnover subcategory of the Scheduling/Communication IUSS events. Fifty points were used to develop the trial or initial center line and control limits. The process was not in control. There was one point of the first fifty that fell beyond the upper control limit. In addition there were seven instances when at least two of three consecutive points fell between the two sigma warning limits and the lower control limit. As this was retrospective data and no investigation could take place regarding the out of control points, the initial limits were not revised. These initial control limits were extended to the remainder of the data. The process remained out of control. Investigating and discovering the reason(s) for extended periods of time between IUSS events then replicating those circumstances or implementing those practices should improve the process. Likewise investigating the reason why there are 0 days between IUSS events due to the turnover of items and working to prevent the need to turn over items can help improve the process. If the events that led to 0 day periods between IUSS events were not due to emergencies, then better coordination with between, the OR, and SPD may help improve the process. In addition, monitoring the instruments and sets that are frequently turned over and purchasing additional instruments/sets would reduce the need for IUSS.

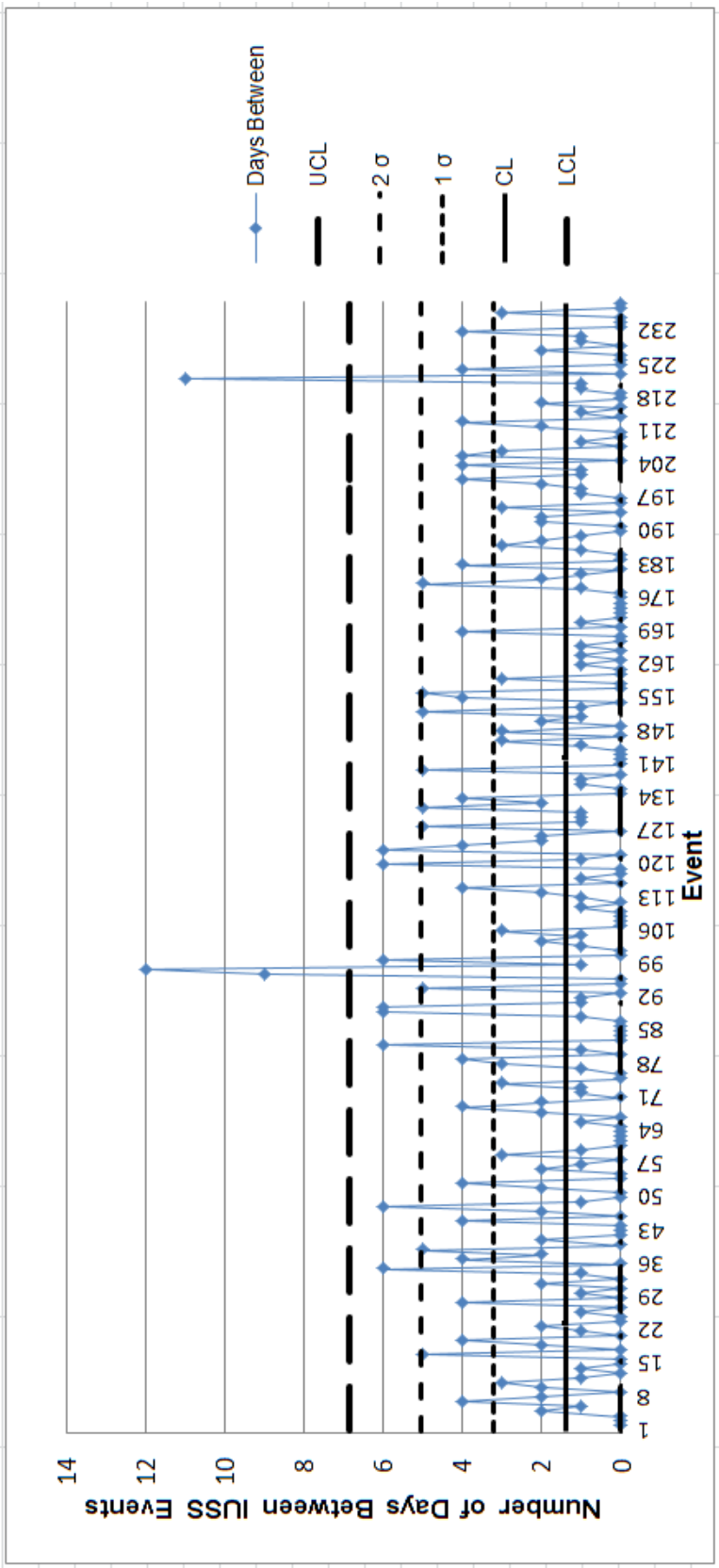

Figure 7 g chart for Days Between IUSS Events

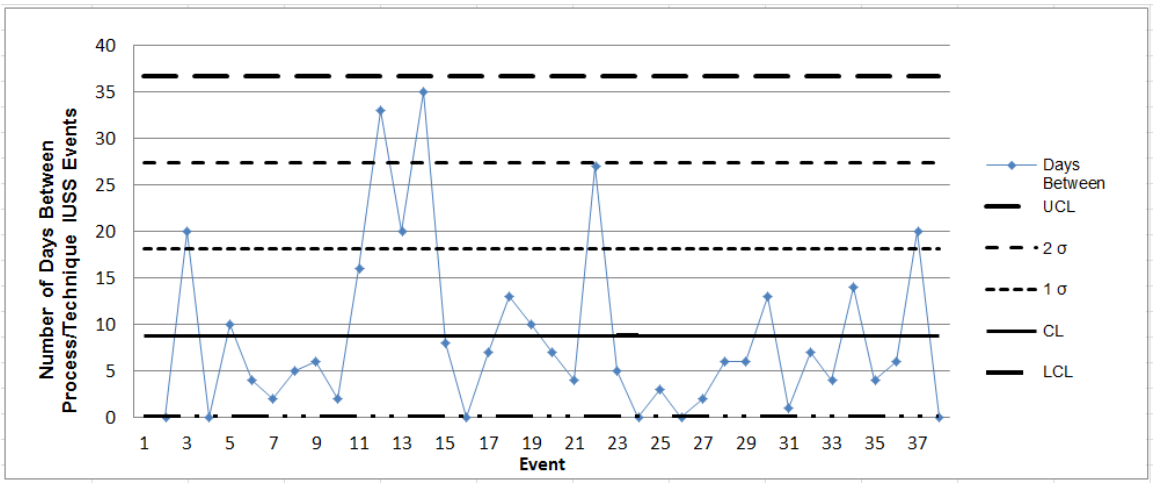

Figure 8 g chart for Days Between Processing/Technique IUSS Events

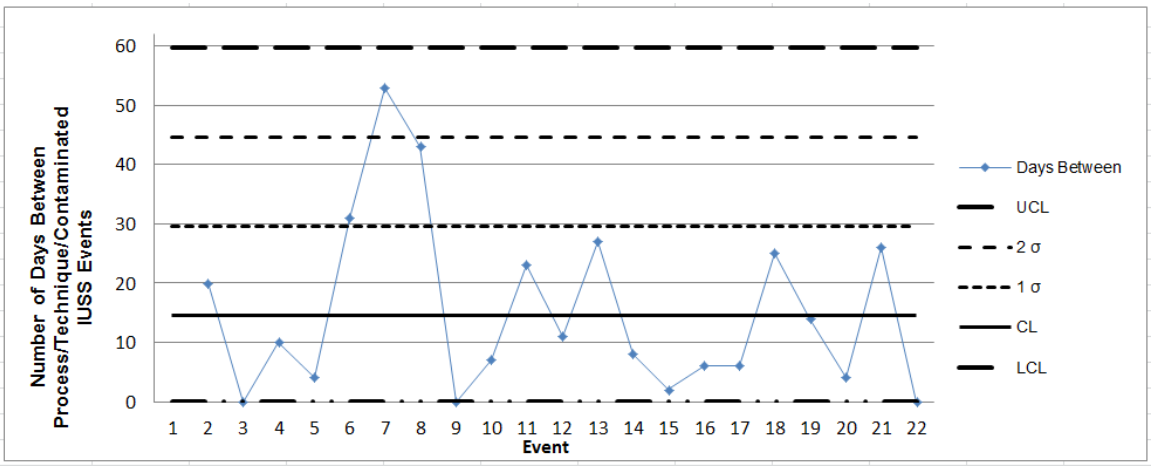

Figure 9 g chart for Days Between Processing/Technique/Contaminated IUSS Events

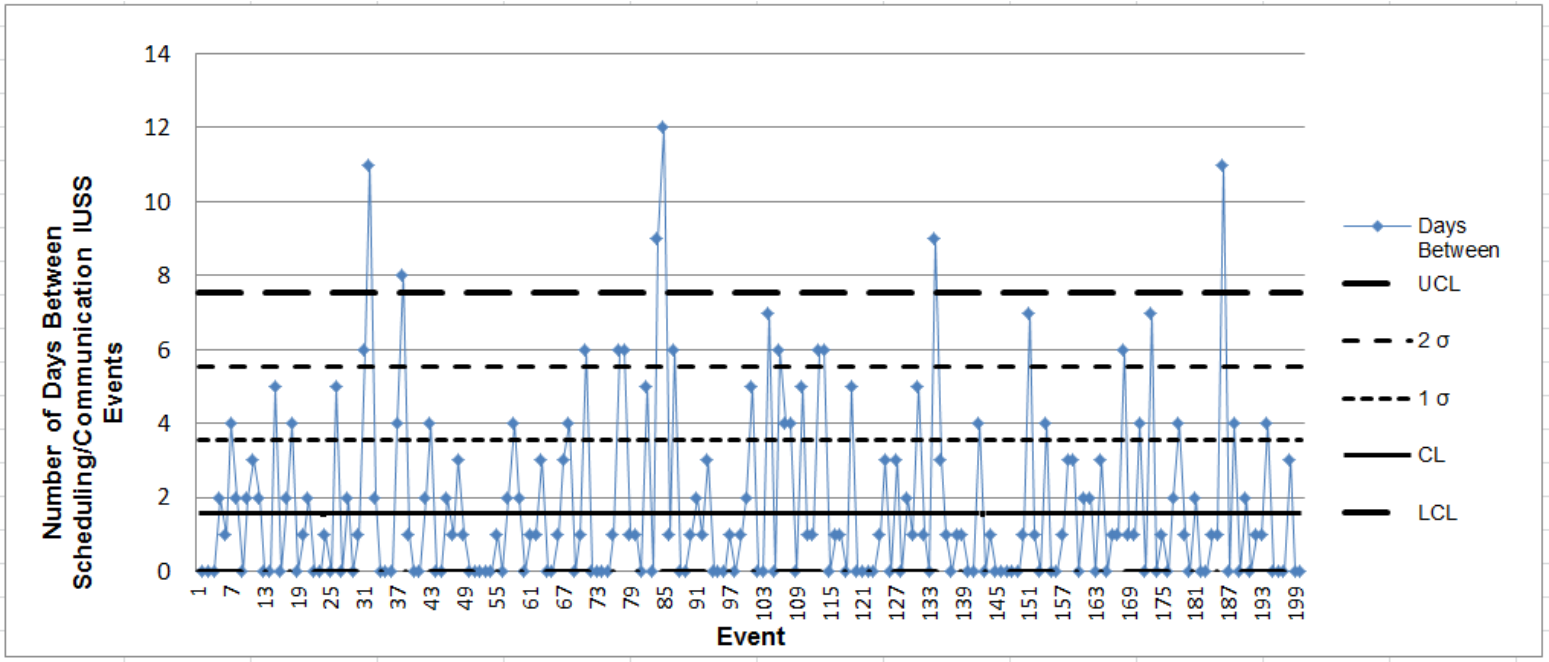

Figure 10 g chart for Days Between Scheduling/Communication IUSS

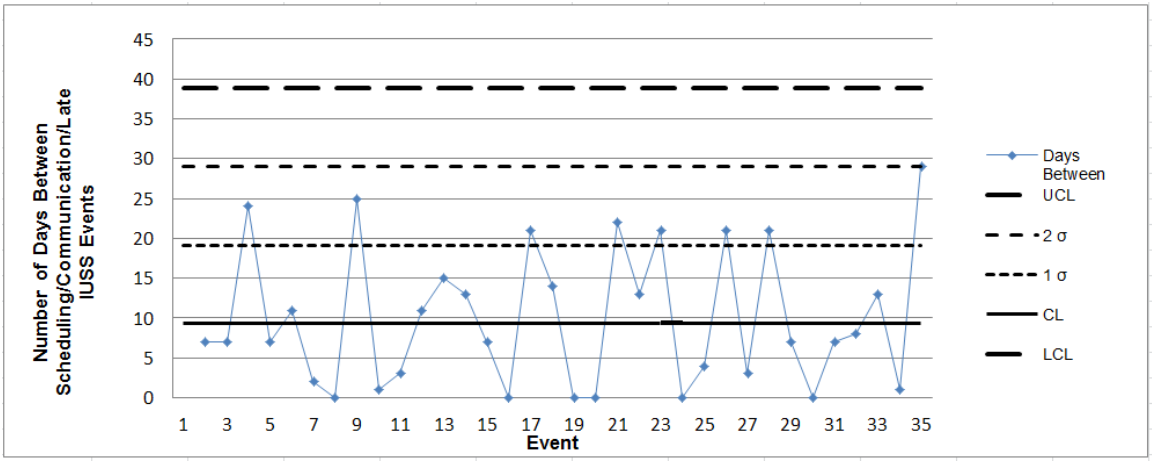

Figure 11 g chart for Days Between Scheduling/Communication/Late IUSS Events

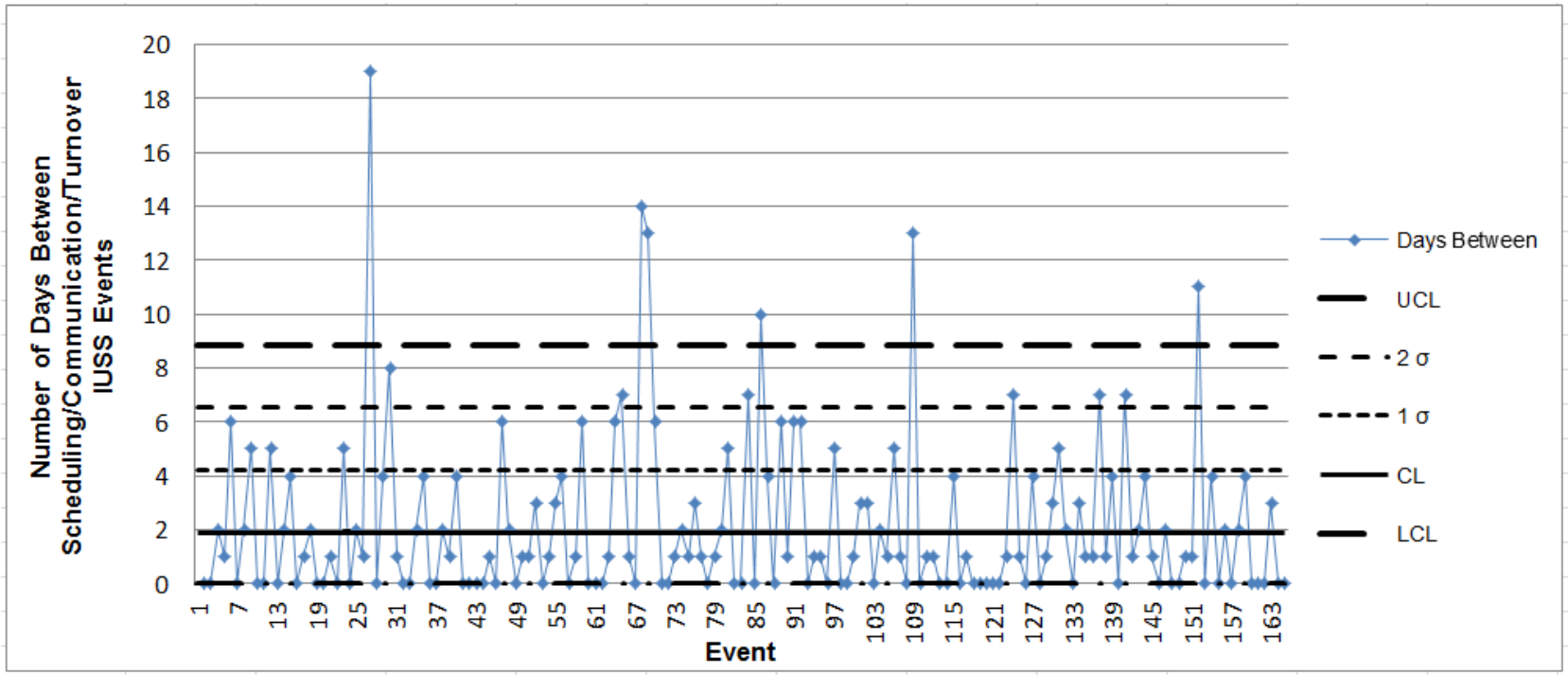

Figure 12 g chart for Days Between Scheduling/Communication/Turnover

4.5 Discussion of Geometric Control Charts for IUSS

Overall the IUSS process is not in control. When the process was stratified, neither of the main categories, Processing/Technique or Scheduling/Communication, were in control. Stratifying further, only the Processing/Technique/Contaminated subcategory was in control. The Scheduling/Communication/Late subcategory and Scheduling/Communication/Turnover subcategories were not in control. There were not enough Package Integrity or Other IUSS events to create a graph for the Processing/Technique/Package Integrity or Processing/Technique/Other subcategories. Working to bring both subcategories of the Scheduling/Communication category into control must occur before the process can be improved.

The largest opportunities to bring the process under control can be realized by reducing the need to turnover instruments and reducing the number and frequency of loaner sets that arrive with insufficient time to terminally sterilize loaner sets. While less impactful, but still important is the need to identify which items are routinely contaminated during surgery. Reviewing the IUSS logs should provide this information. Identifying the specific instruments that are routinely turned over, arrive late, or are contaminated will help bring the process under control. Unfortunately log entries are often vague, which is the case with the data for this project. As many of the entries were vague, it was difficult to determine all potential opportunities, but a review of the information provided did show that the majority of IUSS items were hospital owned with many of the items appearing to be general surgical instruments.

Once the instruments are identified, several strategies can be executed to bring the process under control. First, having an adequate number of replacement general surgical instruments available will reduce the need to turn over the commonly contaminated general instruments. Second, purchasing additional items that are routinely turned over due to scheduling/communication issues should reduce the need for IUSS. Since instrumentation is expensive, capital funds may be required. Third, improving communication regarding scheduling can also help improve the process. For example, if a surgeon does several consecutive knee surgeries, there could be insufficient time to reprocess instruments between knee surgeries. If, in contrast, an orthopedic surgeon schedules a knee, a hip, then another knee surgery, then more

time is available to reprocess the instruments for the second knee surgery. A fourth option is working with vendors to have more loaner sets available on heavy orthopedic days, thus reducing the need to turnover instruments. Lastly, working with vendors to ensure loaner sets are received with sufficient time to properly process and terminally sterilize the loaner sets should also help bring the process under control. Once a process is in control, a concerted effort must be made to fundamentally change the process to realize improvement.

Revising the IUSS log that is kept and maintained by the OR, communicating the importance of providing sufficient detail, and reviewing the log regularly can lead to more actionable information in the future. The challenge with revising the IUSS log to facilitate improved data collection is understanding the pace at which an OR operates and not be overburdening the OR with data collection. The data for this project was from a hospital that recorded all information manually. For hospitals that have tracking systems, the ability to scan the instruments/sets to the autoclaves in the OR can provide the necessary detail to help the OR make informed decisions about future equipment purchases and scheduling sequences.

CHAPTER 5

THE ROLE OF DATA MINING

5.0 Role of Data Mining

There are many definitions for data mining. Each definition touches upon the same components: 1) data mining is an interdisciplinary field that combines concepts and methods from statistics and computer science, 2) data mining seeks to discover useful information from large data sets, and 3) the data sets used for data mining are often observational data sets (Tan, Steinbach, and Kumar 2006; Yoo et al. 2012; Koh and Tan 2005). Additionally, data mining is a crucial step in knowledge discovery in databases (KDD) (Tan, Steinbach, and Kumar 2006; Yoo et al. 2012). Although the steps of KDD can be defined differently, the process identifies the necessary raw data, combines data from different sources as necessary, cleans or scrubs the data, selects the appropriate features, mines the data, then interprets and formats the results to allow for informed decision making.

While both statistics and data mining are based on mathematics, statistics and data mining have several differences. First, in contrast to statistics conservative mathematical approach, data mining provides flexibility in the methods used to analyze data and also adopts heuristics to process the data. Second, statistics generally use a sample of the data from a population while data mining generally uses all of the data from a population. Third, data mining is able to analyze a variety of data including text, images, and sound in contrast to statistics, which focuses on numerical data. Lastly, statistics moves from the general to the specific while data mining moves from the specific to the general (Yoo et al. 2012). In statistics a hypothesis is developed, the data collected, and the hypothesis is tested. Data mining explores data that has already been collected and seeks to discover knowledge in the form of patterns or associations that had not been previously recognized.

5.1 Data Mining in Healthcare

Healthcare data mining applications include fraud detection, evaluation of treatment effectiveness, management of healthcare, and customer relationship management. An example of a healthcare fraud detection application is the 1998 Texas Medicaid Fraud and Abuse

Detection System that recovered $2.2 million and identified 1,400 suspects for investigation (Koh and Tan 2005). Yoo et al. (2012) site a SAS case study where the insurance company Highmark, a Blue Cross Blue Shield affiliate, built a fraud detection system. The classification system allows Highmark to react to unusual activity in a timely manner. Timely follow-up of the fraud detection system findings resulted in $11.5 million in savings for Highmark in 2005. An additional benefit from the automated classification system is that the workload of the investigators has been reduced (Yoo et al. 2012). Comparing outcomes of patient groups treated with different drug regimens for the same disease or condition to evaluate which treatment works best is an example of how data mining can evaluate treatment effectiveness. For the management of healthcare, Koh and Tan (2005) site Blue Cross's use of emergency department and hospitalization claims data, pharmaceutical records, and physician interviews to identify unknown asthmatics and develop appropriate interventions. Yoo et al. (2012) site a second SAS case study by Highmark to show the application of data mining to the management of healthcare. Highmark developed the Security Blue Reimbursement Model, a decision tree model. The inputs into the Security Blue Reimbursement Model include patient symptoms, health history, and demographics to predict a patient's risk then ranks patients for thirteen diseases. The purpose of ranking patients is to identify under-diagnosed patients. Early diagnosis and intervention lowers healthcare costs because CMS reimbursement is dependent upon diagnosis. (Yoo et al. 2012). An example of healthcare data mining applied to customer relationship management is the Consumer Healthcare Utilization Index that was developed by the Customer Potential Management Corp. This index was developed by using millions of healthcare transactions of several million patients. "The index has been used by OSF Saint Joseph Medical Centre to get the right messages and services to the most appropriate patients at strategic time" (Koh and Tan 2005).

5.2 Challenges with Healthcare Data for Data Mining

Mining healthcare data presents several challenges. According to Yoo et al. (2012), these challenges include inferior data quality, patient privacy requirements, and legal considerations.

Healthcare data can be considered inferior due to the nature of healthcare. Healthcare data can have an abundance of missing values. Missing values can occur because patients may undergo different examinations and tests to reach their diagnoses. Factors that cause different paths to be taken include a patient's age, family history, risk factors, and symptoms. In addition, healthcare data may be time dependent, meaning that the relationship of testing and examinations may be important to the diagnosis and treatment of a condition or disease. As much of healthcare data is observational, acquired to meet business needs of billing and finance, the data may not have clinical relevance. The lack of complete Electronic Medical Records (EMR) contributes to the third reason for missing data. Paper based test results and physician's notes may not be available electronically. Additionally, a patient's historical records may not be available electronically or may have scanned into the EMR. Scanned digital data may require significant preprocessing to be available for data mining.

Privacy concerns and requirements regarding patient information is a second challenge regarding healthcare data. The confidentially of patient information can be preserved by coding or de-identifying patient information. The Health Insurance Portability and Accountability Act (HIPAA) regulations require that a patient's private information be protected.

Lastly, healthcare data must be treated with care because of legal concerns. Should a data mining project discover a medical error, a lawsuit could be initiated against the healthcare providers.

5.3 Data Mining Applications for Sterile Processing Data

As healthcare organizations adopt tracking systems, as these tracking systems are interfaced with the equipment used in the reprocessing cycle (washers, incubators, autoclaves), as the tracking systems are interfaced with HIMS such as scheduling and EMR, and as data warehouses are built, the application of data mining for instrument reprocessing information can be expanded. Interfacing instrument tracking systems and EMR will accomplish the goal of tracking instruments to patients set by AAMI (AAMI 2010). The mining of this linked data may uncover unique, subtle, or complex patterns that could improve patient care and/or operational efficiencies. Data mining may identify risks for surgical site infections for improved patient care.

Exploring the relationship between instrumentation and OR on-time starts could help improve OR room turnaround times. As stated earlier, the OR contributes to the financial success of a healthcare organization. Reducing the OR turnaround time can increase the number of surgeries that can be performed each day and contribute to the financial success of an organization.

Due to the difficulties and unavailability of a data set from integrated systems, two existing data sets were merged into a simple fictitious data set. The objective is to illustrate a possible application. The results should not be viewed for analysis, but merely as an illustration the data mining potential that exists with medical device tracking system data.

A simple example is presented using a fictitious data set created from two existing data sets. The first data set was extracted from an instrument tracking system. A second data set containing immediate use steam sterilization data was inserted into the first data set. While the data sets are from two different healthcare organizations, the data can be combined because hospitals generally have the same types of instrumentation (orthopedic, general, neurological, cardiovascular, and gynecological).

5.4 Data Description

The data from the two sources were combined and preprocessed. The first data set was comprised of the date and time stamp of individual instruments and instrument sets as they traveled through the instrument reprocessing cycle (clean, assemble, sterilize, store, and distribute). As the barcode on an instrument/instrument set was scanned at each step/location, the tracking system recorded a date and time stamp. Table 5 shows examples of the data that was extracted from an instrument tracking system. The second data set contained information about the IUSS items. Table 6 shows an IUSS log listing the day of the IUSS, a description of the item that underwent IUSS, and the sterilizer in which the IUSS took place. Twenty-eight incidents of IUSS were inserted into the data set from the tracking system. The Action, User, and Quantity columns were removed from the combined data set. In addition, three columns were added. The weekday showing the day of the week on which the IUSS occurred, the owner of the instrument/instrument set, and the type of sterilization (IUSS or terminal) were added to the combined data set. Lastly, the time was extracted from the date/time column of the first data set

from an instrument tracking system. Separating the time from the date allowed the time of day that an item was processed to be considered as a variable when the decision tree was being constructed. Table 7 shows some rows from the combined data set. The resulting data set contained 6,211 lines of data. The variables that were included in the data mining example are summarized in Table 8.

Table 5 Data Extracted from Instrument Tacking System

	A	B	C	D	E	F	G	H
1	**Description**	**Name**	**Location type**	**Location**	**Action**	**Date / time**	**User**	**Qty**
2	BNI CRANIOTOMY SET	BNICRANI-004	BNI DISTRIBUTION CART	BNI DISTRIBUTION CART	Recvd	10/1/2009 0:08	SPD Staff Q	1
3	CTOR PEDS OPEN HEART TRAY	CVSOPHRTP-001	CVOR DISTRIBUTION CART	CVOR DISTRIBUTION CART	Recvd	10/1/2009 0:09	SPD Staff Q	1
4	L&D HOUSE SET	LDXHOUSE-022	L&D DISTRIBUTION CART	L&D DISTRIBUTION CART	Recvd	10/1/2009 3:10	SPD Staff Q	1
5	GS HAND TRAY	GENHAND-001	Assembly	Assembly	Recvd	10/1/2009 3:10	SPD Staff EF	1
6	GS SYNTHES LARGE BATTERY DRIVE	GENSLBDRV-001	Assembly	Assembly	Recvd	10/1/2009 3:11	SPD Staff X	1
7	BNI CRANIOTOMY SET	BNICRANI-011	Sterilizer 1	Sterilizer 1	Recvd	10/1/2009 3:14	SPD Staff Q	1
8	GS MICROSCOPE HANDLES SET OF 3	GENMCSHND-001	Assembly	Assembly	Recvd	10/1/2009 3:15	SPD Staff Z	1
9	L&D C-SECTION TRAY	LDXCSECTN-012	L&D	L&D	Recvd	10/1/2009 3:17	OR Staff S	1
10	L&D DISTRIBUTION CART (GENERIC)	LDDSTBCTG-001	L&D DISTRIBUTION CART	L&D DISTRIBUTION CART	Recvd	10/1/2009 11:47	SPD Staff T	1
11	GS LAPAROTOMY TRAY	GENLAPARO-007	Decontam	Decontam	Recvd	10/1/2009 11:49	SPD Staff V	1
12	BNI LIGHT HANDLE SET	BNIXLHSET-002	Assembly	Assembly	Recvd	10/1/2009 11:55	SPD Staff D	1
13	GSOR DISTRIBUTION CART (GENERIC)	GSDTRBCTG-001	GSOR	GSOR	Recvd	10/1/2009 12:02	SPD Staff T	1
14	GS PERCUTANEOUS PINNING SET	GENPRCPNS-001	Decontam	Decontam	Recvd	10/1/2009 12:04	SPD Staff V	1
15	BNI LIGHT HANDLE SET	BNIXLHSET-002	Assembly	Assembly	Recvd	10/1/2009 12:08	SPD Staff D	1
16	GS PADGETT DERMATOME TRAY	GENPGDERM-001	Sterilizer 9	Sterilizer 9	Recvd	10/1/2009 12:10	SPD Staff T	1
17	GS PADGETT DERMATOME TRAY	GENPGDERM-002	Sterilizer 9	Sterilizer 9	Recvd	10/1/2009 12:10	SPD Staff T	1
18	ADULT ECHO LAB - ADULT TEE PROBE	ADECOADPB-005	Decontam	Decontam	Recvd	10/1/2009 12:11	SPD Staff V	1
19	GS LAPAROTOMY TRAY	GENLAPARO-016	Assembly	Assembly	Recvd	10/1/2009 12:11	SPD Staff D	1
20	PEDS ECHO LAB-PEDS TEE PROBE	PEDECOPPB-001	Decontam	Decontam	Recvd	10/1/2009 13:15	SPD Staff V	1
21	GS STRYKER 4100 CORDLESS DRIVER	GENST4100-002	INCOMPLETE CART	INCOMPLETE CART	Recvd	10/1/2009 13:17	SPD Staff GH	1
22	GS THREADED STEINMANN PINS	GENSTPINT-001	Assembly	Assembly	Recvd	10/1/2009 13:18	SPD Staff C	1
23	GS DRILL BIT BOX	GENX00427-002	GSOR DISTRIBUTION CART	GSOR DISTRIBUTION CART	Recvd	10/1/2009 16:48	SPD Staff F	1
24	CTOR GRAFTING SUCTION 3MM	CVSX00120-001	CVOR DISTRIBUTION CART	CVOR DISTRIBUTION CART	Recvd	10/1/2009 16:48	SPD Staff F	1
25	GS SYNTHES PLIERS (391.82)	GENXSPLIR-001	GSOR DISTRIBUTION CART	GSOR DISTRIBUTION CART	Recvd	10/1/2009 16:49	SPD Staff F	1
26	GS PEDIATRIC ORTHO SET	GENPORTHO-006	GSOR	GSOR	Recvd	10/1/2009 20:17	OR Staff L	1
27	GS STEINMANN PIN TRAY	GENSTEINP-001	GSOR	GSOR	Recvd	10/1/2009 20:17	OR Staff L	1

Table 6 IUSS Log Showing IUSS Items, Reason for IUSS, and Sterilizer Number

MONTH & YEAR: SEPTEMBER 2011

DAY	DESCRIPTION	FLASHING REASON	PATIENT LAST NAME	FLASHER #
4	COMPANY INSTRUMENT	FELL OUT OF STERILE FIELD		4
9	TRIALS FOR BIOMET HIP	LATE ARRIVAL FOR HIP REVISION		4
9	TRIALS FOR BIOMET HIP	RERUN PREVIOUS LOAD DUE TO WRONG CYCLE		4
9	TRABUCULAR METAL TRAY	FOUND HOLE IN WRAPPER		4
12	ORTHO SIZER	FELL OUT OF STERILE FIELD		5
12	DEPUY FB MARCRO TRIAL	TRAY FROM ANOTHER FACILITY		4
12	BROACH HANDLE	TRAY WRAP HOLE IN HAD OPEN TRAY AND TAKE		4
		OUT OF UNSTERILE BROACH HANDLE		
13	ARTHREX CRAIG SET	UNSTERILE		4
13	ARTHREX SHAVER	UNSTERILE		4
14	FREEMAN RETR.	FELL ON FLOOR		5
14	SCREWDRIVER	UNSTERILE		5
15	FREEMAN RETR.	NEED FOR CASE		5
15	BIOMET RETRACTOR	UNSTERILE		4
15	BIOMET RETRACTOR	TURN OVER		4
19	3 DRILL BITS AND FEMORAL NECK ELEVATOR	NEED FOR CASE		4
20	90 DEGREE HOHNMAN RIGHT ANGLE	NOT STERILE		4
20	90 DEGREE HOHNMAN RIGHT ANGLE	NOT STERILE		4
20	INSTRUMENT DR. SHARPE	INSTR. TURNOVER		4
20	DIANA DROPPED INSTR. TRAY	NEED TO FLASH		4
20	INSTRUMENT	NEED STERILE		4
20	INSTRUMENT	USED PREVIOUS CASE		4
20	RADIOLUCENT DRILL	INSTRUMENT WASN'T TURNOVER		4
21	FEMORAL NECK ELEVATOR	NOT STERILE		5
26	ANKLE CLAMP	FELL ON FLOOR NEED FOR CASE NOT USED		4
28	SPIDER SHOULD BAR	NOT STERILE		4
29	SPIDER SHOULDER BAR	NOT STERILE		4
29	INSTRUMENT	NOT STERILE		7

Table 7 IUSS Combined Data Set for Data Mining Example

	A	B	C	D	E	F	G	H	I	J
1	Description	Name	Location type	Location	Date	Time	Weekday	Specialty	OWN	IUS
5559	GS PIN CUTTER	GENX00618-002	Sterilizer	Sterilizer 4	10/04/09	12:37:50 AM	1	GEN	0	0
5560	GS FERRIS SMITH TISSUE FORCEP	GENX00438-001	Sterilizer	Sterilizer 4	10/04/09	12:37:52 AM	1	GEN	0	0
5561	GS COOLEY STERNUM RETRACTOR	GENCOOLEY-001	Sterilizer	Sterilizer 4	10/04/09	12:37:54 AM	1	GEN	0	0
5562	BNI NEW GREENBERG RETRACTORS	BNIGBRG2-002	Sterilizer	Sterilizer 4	10/04/09	12:37:55 AM	1	BNI	0	0
5563	BNI LEYLA BAR	BNIXLEYLA-003	Sterilizer	Sterilizer 4	10/04/09	12:37:57 AM	1	BNI	0	0
5564	BNI RHOTON DISSECTORS X 15	BNIRHTX15-002	Sterilizer	Sterilizer 4	10/04/09	12:38:00 AM	1	BNI	0	0
5565	GS COOLEY RETR ADULT SHORT BLADES	GSXCOOLSH-001	Sterilizer	Sterilizer 4	10/04/09	12:38:03 AM	1	GEN	0	0
5566	GS SYNTHES SMALL CERCLAGE WIRE INSTRUMENTS	GENSSCERC-002	GSOR	GSOR	10/04/09	1:03:09 AM	1	GEN	0	0
5567	GS STRYKER 4100 CORDLESS DRIVER	GENST4100-001	GSOR	GSOR	10/04/09	1:03:10 AM	1	GEN	0	0
5568	GS STRYKER 4100 CORDLESS DRIVER	GENST4100-001	GSOR	GSOR	10/04/09	2:33:35 AM	1	GEN	0	0
5569	GS SYNTHES SMALL CERCLAGE WIRE INSTRUMENTS	GENSSCERC-002	GSOR	GSOR	10/04/09	2:33:37 AM	1	GEN	0	0
5570	L&D HOUSE SET	LDXHOUSE-002	Decontam	Decontam	10/04/09	4:48:42 AM	1	LD	0	0
5571	L&D HOUSE SET	LDXHOUSE-003	Decontam	Decontam	10/04/09	4:48:46 AM	1	LD	0	0
5572	L&D HOUSE SET	LDXHOUSE-035	Decontam	Decontam	10/04/09	4:49:00 AM	1	LD	0	0
5573	L&D HOUSE SET	LDXHOUSE-006	Decontam	Decontam	10/04/09	4:49:05 AM	1	LD	0	0
5574	L&D HOUSE SET	LDXHOUSE-040	Decontam	Decontam	10/04/09	4:49:13 AM	1	LD	0	0
5575	L&D HOUSE SET	LDXHOUSE-007	Decontam	Decontam	10/04/09	4:49:31 AM	1	LD	0	0
5576	L&D HOUSE SET	LDXHOUSE-027	Decontam	Decontam	10/04/09	4:49:43 AM	1	LD	0	0
5577	L&D C-SECTION TRAY	LDXCSECTN-007	L&D	L&D	10/04/09	4:51:45 AM	1	LD	0	0
5578	L&D C-SECTION TRAY	LDXCSECTN-013	L&D	L&D	10/04/09	4:51:49 AM	1	LD	0	0
5579	L&D C-SECTION TRAY	LDXCSECTN-004	L&D	L&D	10/04/09	4:51:52 AM	1	LD	0	0
5580	L&D C-SECTION TRAY	LDXCSECTN-012	L&D	L&D	10/04/09	4:51:58 AM	1	LD	0	0
5581	L&D C-SECTION TRAY	LDXCSECTN-003	L&D	L&D	10/04/09	4:52:01 AM	1	LD	0	0
5582	L&D DR. MOUERS MCLANE-TUCKER OBSSETRICAL FORCEPS	LDXX00780-001	L&D	L&D	10/04/09	4:52:06 AM	1	LD	0	0
5583	L&D LIGHT HANDLE SET	LDXX00795-017	L&D	L&D	10/04/09	4:52:12 AM	1	LD	0	0
5584	L&D LIGHT HANDLE SET	LDXX00795-010	L&D	L&D	10/04/09	4:52:15 AM	1	LD	0	0
5585	L&D LIGHT HANDLE SET	LDXX00795-023	L&D	L&D	10/04/09	4:52:21 AM	1	LD	0	0
5586	L&D LIGHT HANDLE SET	LDXX00795-012	L&D	L&D	10/04/09	4:52:26 AM	1	LD	0	0
5587	L&D LIGHT HANDLE SET	LDXX00795-015	L&D	L&D	10/04/09	4:52:30 AM	1	LD	0	0
5588	L&D HOUSE SET	LDXHOUSE-016	L&D	L&D	10/04/09	4:52:36 AM	1	LD	0	0
5589	L&D HOUSE SET	LDXHOUSE-014	L&D	L&D	10/04/09	4:52:40 AM	1	LD	0	0

Table 8 Data Mining IUSS Variable Summary

Variable	Description	Data Type	Values
Sterilization Type	Sterilization category	Nominal	0=Terminal, 1=IUSS
Owner	Instrument Ownership	Nominal	0=Hospital, 1=Vendor
Specialty	Surgical Specialty to which the item belongs	Nominal	26
Weekday	Day of the week that the item was processed	Categorical	1 through 7
Hour	Hour of the day that the item was sterilized	Categorical	0 through 23
Name	Item name	Nominal	1005

The goal of this example is to classify the sterilization type of an item as immediate use or terminal. This data set is an imbalanced data set because the class of interest, IUSS, is a rare event. There are several strategies for handling imbalanced data including oversampling the minority class, under sampling the majority class, and assigning a misclassification cost ratio (MCR) value. Roumani et al. (2013) found that "the use of MCR for analyzing imbalanced medical data significantly improved the method's classification performance" (Roumani et al. 2013). Following this approach, a MCR of 100 was applied to the misclassification of the minority class (IUSS) as the majority class (terminal sterilization).

IBM SPSS Statistics 22 was used to generate the decision tree. The QUEST (Quick, Unbiased, Efficient, Statistical Tree) algorithm was used to grow the tree. A misclassification cost of 100 was applied to misclassifying the minority target class (IUSS) as terminal sterilization. Fivefold cross validation was employed for validating the tree. Table 9 below summarizes the model and results.

Table 9 Decision Tree Model Summary for IUSS

Model Summary

Specifications	Growing Method	QUEST
	Dependent Variable	Sterilization Type
	Independent Variables	Owner, Specialty, Weekday, Hour, Name
	Validation	Cross Validation
	Maximum Tree Depth	5
	Minimum Cases in Parent Node	100
	Minimum Cases in Child Node	50
Results	Independent Variables Included	Owner, Hour, Specialty, Weekday, Name
	Number of Nodes	11
	Number of Terminal Nodes	6
	Depth	3

5.5 Data Mining Results and Discussion

Referring to Figure 13, the decision tree that was generated has a depth of three layers with six terminal nodes. The tree algorithm determined that Owner, Hour, and Specialty were significant factors in predicting IUSS. Table 10 shows the gains table for the six terminal nodes. The largest gains were made on nodes 8, 6, and 9. The confusion matrix in Table 11 shows the overall percent correct as 89.0%, confirming that using a misclassification ratio for this unbalanced data was an appropriate method.

While this example is a simple model developed from fictitious data set, data generated from the instrument reprocessing cycle can in incorporated into healthcare data mining projects. As data sources become more integrated and as healthcare continues moving toward EMR, sterile processing process data will become more accessible and relevant.

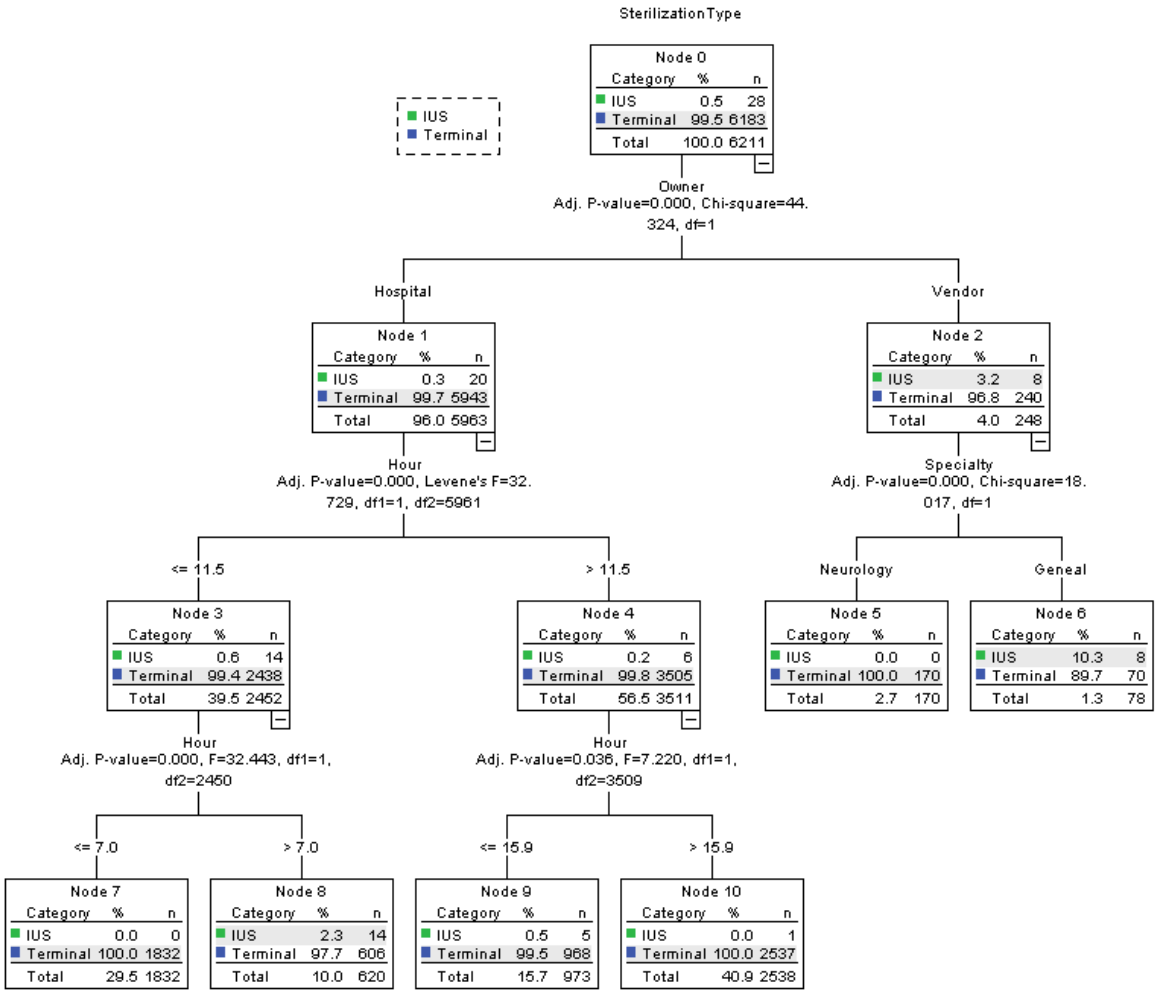

Figure 13 Decision Tree for IUSS

Table 10 Gains Table for IUSS Decision Tree

Gains for Nodes

	Node		Gain			
Node	N	Percent	N	Percent	Response	Index
6	78	1.3%	8	28.6%	10.3%	2275.1%
8	620	10.0%	14	50.0%	2.3%	500.9%
9	973	15.7%	5	17.9%	0.5%	114.0%
10	2538	40.9%	1	3.6%	0.0%	8.7%
7	1832	29.5%	0	0.0%	0.0%	0.0%
5	170	2.7%	0	0.0%	0.0%	0.0%

Table 11 Confusion Matrix for IUSS Decision Tree

Classification

	Predicted		
Observed	IUSS	Terminal	Percent Correct
IUSS	22	6	78.6%
Terminal	676	5507	89.1%
Overall Percentage	11.2%	88.8%	89.0%

Growing Method: QUEST

Dependent Variable: Sterilization Type

CHAPTER 6

6 CONCLUSIONS AND FUTURE WORK

6.1 Conclusions

The demands on healthcare organizations to provide quality services at reasonable prices will continue. The OR is a major contributor to both revenue and expenses for healthcare organizations. Given the relationship and structure of healthcare organizations, SPD's role as an OR support function is critical to the success of the OR and, by extension, to a healthcare organization's ability to meet and hopefully exceed financial and patient safety goals. Effective management of surgical instruments by reducing the incidence of IUSS is one way that an organization can positively impact their financial and patient safety goals. The application of SPC to IUSS can help an organization understand, manage, and improve its IUSS process. Fraction nonconforming (p charts) and time between (g charts) control charts can be developed to help understand, manage, and improve the IUSS process.

Specifically, the results of this work aligned with other works (Smart, Belkoff, and Mears 2012; Leonard et al. 2006), concluding that turning over instruments is the major reason for IUSS. The IUSS process at the organization studied is not in control. Improved communication and coordination between the OR, SPD, and vendors must occur to bring the process under control. Investigating the reason(s) that necessitates the turnover of instruments and type of instrumentation that are frequently turned over will help bring the process under control. Insufficient inventory and scheduling conflicts are often reasons that require the turnover of instruments and IUSS. The late arrival of vendor owned instruments also contributes to the rate and frequency of IUSS. Improved communication and enforcement of hospital policies regarding loaner instrumentation would help bring the IUSS process under control. Reviewing the circumstances that lead to instrument contamination during surgery and working toward having backup instrumentation available would help bring the IUSS process as a whole under control, but would also improve the subcategory of Processing/Technique/Contamination IUSS. Understanding, managing, and improving the instrument reprocessing in a hospital setting can have a positive impact on the moral of the OR and SPD staff, the success of the healthcare

organization, and safety of patients. Data mining and SPC can be used to understand, manage, and improve the instrument reprocessing process.

Implementation of SPC in SPD will require a partnership between SPD and other functions that have the expertise to gather and analyze the process data then create and help monitor the control charts. The Process Improvement, Quality and/or the Infection Control functions of an organization might have the expertise. Organizations that employ industrial engineers would have the expertise. Once established, the control charts can be presented at infection control committee and surgical services meetings in addition to the SPD and OR staffs. The information that is monitored in the logs (date, item, reason) and the information gained from the investigation of events can be used to help an organization reduce the IUSS events, thus, bring the process into control then improve the process. Again, reducing IUSS events should help an organization reach and hopefully exceed patient safety and financial goals.

6.2 Future Work

This work considered the application of SPC and data mining to SPD data. The application of SPC to other areas of SPD, such as monitoring errors and time between equipment breakdowns are possible extensions to this work. The equipment used for instrument reprocessing is expensive and vital to the success of the instrument reprocessing process. As more hospitals adopt instrument tracking systems and as these systems become integrated with other HIMS, more data mining opportunities will become available. Opportunities for exploring the relationship of surgical instrument reprocessing and HAI and OR room turnover efficiencies will exist. SPD provides vital ancillary services to the OR and by extension to its healthcare organization. Accessing and using SPD data will benefit SPD, the OR which it services, the healthcare organization as a whole, and ultimately the patient.

REFERENCES

Association for the Advancement of Medical Instrumentation. 2010. *ANSI/AAMI ST79: 2010 & A1:2010 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. Arlington, VA: Association for the Advancement of Medical Instrumentation.

Benneyan, James C. 1998a. "Statistical Quality Control Methods in Infection Control and Hospital Epidemiology, Part I: Introduction and Basic Theory." *Infection Control and Hospital Epidemiology* 19. no. 3: 194-214.

Benneyan, James C. 1998b. "Statistical Quality Control Methods in Infection Control and Hospital Epidemiology, Part II: Chart Use, Statistical Properties, and Research Issues." *Infection Control and Hospital Epidemiology* 19, no. 4: 265-83.

Benneyan, James C. 2001. "Number-Between g-Type Statistical Quality Control Charts for Monitoring Adverse Events." *Health Care Management Science* 4, no. 4: 305-18.

Benneyan, James C. and Frank C. Kaminsky.1994. "Modeling Discrete Data in SPC: The g and h Charts." In ASQC 48th Annual Quality Congress, Las Vegas NV, May 24-26, 1994, 32-42. Milwaukie: American Society for Quality Control.

Benneyan, J. C., R. C. Lloyd, and P. E. Plsek. 2003. "Statistical Process Control as a Tool for Research and Healthcare Improvement." *Quality & Safety in Health Care* 12, no. 6: 458-64.

Brooks, Tim. 2010. "Breaking It Down." *Health Care Purchasing News* 34, no. 10: 74 -76.

Brooks, Tim. May 23, 2011. "Why does it take so Long? The Complex and Indispensable Requirements for Instrument Reprocessing." *Infection Control Today.* Accessed September 16, 2011. http://www.infectioncontroltoday.com/articles/2011/05/the-complex-and-indispensable-requirements-for-instrument-reprocessing.aspx.

Centers for Disease Control and Prevention. “States Required by Law to Report HAI to NHSN”. Centers for Disease Control and Prevention. Accessed May 13, 2013. http://www.cdc.gov/hai/stateplans/required-to-report-hai-NHSN.html.

Frost and Sullivan. n.d. "Driving Operational Improvement in Hospitals through an Advanced Instrument Management System." Frost and Sullivan White Paper. Accessed November 3, 2011. http://www.carefusion.com/pdf/Surgical_Instrumentation/FrostSullivan.pdf.

Gruskay, Jordan, Christopher Kepler, Jeremy Smith, Kristen Radcliff, and Alexander Vaccaro. 2012. "Is Surgical Case Order Associated with Increased Rate After Spine Surgery." *Spine* 37, no. 13: 1170-1174.

The International Association of Healthcare Central Service Material Management. “Certification Survey.” The International Association of Healthcare Central Service Material Management. Accessed October 22, 2011. http://iahcsmm.org/survey/NovDecSurvey/CS_Certification_Survey.html.

The International Association of Healthcare Central Service Material Management. *2007. Central Service Technical Manual*. 7th ed. Chicago: The International Association of Healthcare Central Service Material Management.

Jackson, Richard L. 2002. "The Business of Surgery.” *Health Management Technology* 23, no. 7: 20-2.

Kaminsky, Frank C., James C. Benneyan, Robert D. Davis, and Richard J. Burke. 1992. "Statistical Control Charts Based on a Geometric Distribution." *Journal of Quality Technology* 24, no. 2: 63-9.

Koh, Hian C. and Gerald Tan. 2005. "Data Mining Applications in Healthcare." *Journal of Healthcare Information Management* 19, no. 2: 64-72.

Leonard, Yukiko, Karen G. Speroni, Martin Atherton, Joy Corriher. 2006. "Evaluating Use of Flash Sterilization in the OR with Regard to Postoperative Infections." *AORN J* 83, no. 3: 672 - 80.

Macario, Alex, Terry S. Vitez, Brian Dunn, and Tom McDonald . 1995. "Where are the Costs in Perioperative Care?" *Anesthesiology* 83, no. 6: 1138-1144.

Martin K. and Beck B. 2004. "Surgical Site Infection Prevention: Interventional Epidemiology." abstract. *American Journal of Infection Control* 32, no. 3: E81-82.

Meldi, Diane, Faith Rhoades, and Annette Gippe. 2009. "The Big Three: A Side by Side Matrix Comparing Hospital Accrediting Agencies." *Synergy* January/February 2009: 12 -14. Accessed April 22, 2012. http://www.namss.org/Portals/0/Advocacy/NAMSS_Synergy_JanFeb09_Accreditation_Grid.pdf.

Montgomery, Douglas. C. 2009. *Introduction to Statistical Quality Control*. 6th ed. USA: Wiley.

Narance, David. 2008. "A Scorecard for Sterile Processing Metrics." *OR Manager* 24, no. 7: 15-16.

Richmond, Amy M., Colleen M. Becker, Murray Fields, James M. Thomas, and David K. Warren. 2009. "Flash Sterilization Process Improvement and Correlation with Surgical Site Infections." abstract. *American Journal of Infection Control* 3, no. 5: E124.

Roumani, Yaza F., Jerrold H. May, David P. Strum, and Luis G. Vargus. 2013. "Classifying Highly Imbalanced ICU Data." *Healthcare Management Science* 16, no. 2: 119-28.

Scott, R. Douglas II. 2009. "The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention." Centers for Disease Control and Prevention CDC. Accessed November 3, 2011. http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf

Smart, Julia D., Stephen M. Belkoff, and Simon C. Mears. 2012. "The Effectiveness of a Program to Reduce the Rate of Flash Sterilization." *The Journal of Arthroplasty* 27, no. 7: 1267-70.

Stone, Patricia W. 2009. "Economic burden of healthcare-associated infections: an American perspective." *Expert Review of Pharmacoeconomics and Outcomes Res*earch 9, no. 5: 417–22.

Tan, Pang-Ning, Michael Steinbach, and Vipin Kumar. 2006. "*Introduction to Data Mining*." USA: Addison Wesley.

Thor, Johan, Jonas Lundberg, Jakob Ask, Jesper Olsson, Cheryl Cardli, Karin Härenstam, Mats Brommels. 2007. "Application of Statistical Process Control in Healthcare Improvement: Systematic Review." *Quality & Safety in Health Care* 16, no. 5: 387-99.

Williamson, Julie. 2011. "Vendors, Providers Scan Progress, Potential in Instrumentation Tracking." *Health Care Purchasing News* 34, no. 2: 32 -37.

Yoo, Illhoi, Patricia Alafaireet, Miroslav Marinov, Keila Pena-Hernandez, Rajitha Gopidi, Jia-Fu Chang, and Lei Hua. 2012. "Data Mining in Healthcare and Biomedicine: A Survey of the Literature." *Journal of Medical Systems* 36, no. 4: 2431-48.

Zuckerman, Scott L., Ravi Parikh, David C. Moore, and Thomas R. Talbot. 2012. "An Evaluation of Immediate-Use Steam Sterilization Practices in Adult Knee and Hip Arthroplasty Procedures." *American Journal of Infection Control* 40, no. 9: 866-71.

`